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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1218

CPSC Docket No. CPSC-2010-0028

RIN 3041-AC81

Safety Standard for Bassinets and Cradles

AGENCY: Consumer Product Safety Commission.

ACTION: Supplemental Notice of Proposed Rulemaking.

SUMMARY: The Consumer Product Safety Improvement Act of 2008 (CPSIA) requires the United States Consumer Product Safety Commission (Commission or CPSC) to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. The Commission is proposing a safety standard for bassinets and cradles in response to the CPSIA. This constitutes a second round of notice and comment, or supplemental notice of proposed rulemaking, for bassinets and cradles.

DATES: Submit comments by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Comments related to the Paperwork Reduction Act aspects of the marking, labeling, and instructional literature of the proposed rule should be directed to the Office of Information and Regulatory Affairs, OMB, Attn: CPSC Desk Officer, FAX: 202-395-6974, or e-mailed to oir_submission@omb.eop.gov.

Other comments, identified by Docket No. CPSC-2010-0028, may be submitted electronically or in writing:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: <http://www.regulations.gov>. Follow the instructions for submitting comments. To ensure timely processing of comments, the Commission is no longer directly accepting comments submitted by electronic mail (e-mail), except through www.regulations.gov. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions in the following way: Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>, and insert the docket number, CPSC 2010-0028, into the “Search” box and follow the prompts.

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SUPPLEMENTARY INFORMATION:

A. Background and Statutory Authority

The Consumer Product Safety Improvement Act of 2008, (CPSIA, Pub Law 110-314), was enacted on August 14, 2008. Section 104(b) of the CPSIA, part of the Danny Keysar Child Product Safety Notification Act, requires the Commission to: (1) examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts, and (2) promulgate consumer product safety standards for durable infant and toddler products. These standards are to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. The term “durable infant or toddler product” is defined in section 104(f)(1) of the CPSIA as a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years. Bassinets and cradles are specifically identified in section 104(f)(2)(L) as a durable infant or toddler product.

In April 2010, the Commission issued a notice of proposed rulemaking (NPR) for bassinets and cradles. (75 Fed. Reg. 22303, April 28, 2010). Through ongoing consultation and assessment of the standard, both the ASTM standard and the Commission’s proposals have evolved since publication of the April 2010 NPR, such that the Commission believes a supplemental notice and opportunity for the public to comment would be beneficial. Thus, in

this document, the Commission is proposing a safety standard for bassinets and cradles in a supplemental notice of proposed rulemaking. Pursuant to Section 104(b)(1)(A), the Commission consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public in the development of this proposed standard, largely through the ASTM process. The proposed standard is based on the voluntary standard developed by ASTM International (formerly the American Society for Testing and Materials), ASTM F2194-12, “Standard Consumer Safety Specification for Bassinets and Cradles” (ASTM F2194-12), with additions and modifications to strengthen the standard. The ASTM standard is copyrighted but can be viewed as a read-only document, only during the comment period on this proposal, at: <http://www.astm.org/cpsc.htm>, by permission of ASTM.

B. The Product

ASTM F2194-12 defines a “bassinet/cradle” as a “small bed designed exclusively to provide sleeping accommodations for infants supported by free standing legs, a wheeled base, a rocking base, or which can swing relative to a stationary base” and provides that a bassinet/cradle is “intended to provide sleeping accommodations only for an infant up to approximately 5 months in age or when the child begins to push up on hands and knees, whichever comes first.” ASTM F2194-12 defines a “bassinet/cradle accessory” as “a supported sleep surface that attaches to a crib or play yard designed to convert the product into a bassinet/cradle intended to have a horizontal sleep surface while in a rest (non-rocking) position.” The Commission is proposing modifications to the scope and definition of a bassinet/cradle and bassinet/cradle accessory, as further discussed herein.

C. The Voluntary Standard--ASTM F2194

The voluntary standard for bassinets and cradles was first approved and published by ASTM in 2002, as ASTM 2194, *Standard Consumer Safety Specification for Bassinets and Cradles*. The standard has been revised a number of times since then. The Commission's April 2010 NPR assessed the effectiveness of ASTM F2194-07a^{e1}. Since publication of the 2010 NPR, the standard has been revised three times: in 2010, 2011, and, most recently, in 2012. The 2012 version, ASTM F2914-12, was approved on June 1, 2012. The 2012 voluntary standard contains requirements addressing a number of hazards. The requirements include:

1. Compliance with CPSC's regulations at 16 CFR part 1303 (ban of lead in paint), 16 CFR 1500.48 and 16 CFR 1500.49 (sharp points and sharp edges), and 16 CFR part 1501 (small parts), both before and after the product is tested according to the standard.
2. Exposed wood parts on bassinet/cradles, prior to testing, must be smooth and free of splinters.
3. Bassinets/cradles must not present scissoring, shearing, or pinching hazards.
4. Requirements and test method to prevent unintentional folding.
5. Requirements for the permanency of labels and warnings.
6. Prohibition against using wood screws in the assembly of any components that must be removed by the consumer in the normal disassembly of a bassinet/cradle.
7. Limits on how far a corner post assembly may extend.
8. Prohibition against containing an occupant restraint system when the product is used in the bassinet/cradle mode.
9. Performance requirements for the spacing of rigid sided bassinet/cradle components.

10. Performance requirements for the openings of mesh/fabric sided bassinet/cradles to prevent entrapment.
11. Performance requirements and test methods for static load and stability of the bassinet/cradle.
12. Requirements regarding the thickness and dimensions of the sleeping pad.
13. Requirements for the side height of the bassinet/cradle.
14. Requirements and test method for protective components of bassinet/cradle.
15. Fabric-sided enclosed openings requirement and test method involving a torso probe to protect against entrapment in bounded openings in the bassinet/cradle.
16. Performance requirements and test methods for the rock/swing feature of bassinets or cradles.
17. Marking, labeling, and instructional literature requirements.

D. Incident Data

The CPSC's Directorate for Epidemiology reports that there have been 335 incidents reported to the Commission regarding bassinets/cradles from November 2007 through December 2011. The data is drawn from the CPSC's "Early Warning System" (EWS), a pilot project initiated in 2007, which draws all data entered into the CPSC's epidemiology databases on a weekly basis. The 335 incidents involved 94 fatalities and 241 nonfatal incidents. (Because the number of emergency department-treated injuries associated with bassinets and cradles was insufficient to derive any reportable national estimates, injury estimates are not presented separately but are instead included within the category "nonfatal incidents.").

1. Fatalities

A total of 94 bassinet-related fatalities have been reported from early November 2007 through December 2011. Eight of the 94 deaths are associated with the design aspects of the product. Three of these deaths were due to entrapment and/or hanging that resulted after an infant's body, but not head, slipped through the fabric covering and underlying structural components of a particular brand of convertible bassinets/bedside sleeper that was subsequently recalled for this defect. Two of these three infants were 6 months old, while the third infant was a 4-month-old. Three of the eight deaths are associated with problems dealing with the flatness of the mattress pads used in a bassinet accessory of a play yard. All three of these decedents were 5 months old or younger. One of the three decedents suffocated in the corner of the bassinet when he rolled into that position due to the unlevel mattress pad; the other two decedents were found face down in a dip in the center of the unlevel mattress pad. The rocking feature of a bassinet, which contributed to its non-level resting position, was associated with an additional suffocation death of a 1-month-old infant. The remaining fatality associated with the design of the product occurred when the bassinet bed fell off its stand and allowed the 3-month-old decedent to get pinned between the bassinet and a nearby dresser.

Eighty two of the deaths were asphyxiations due to the presence of soft or extra bedding in the bassinet, prone placement of the infant, and/or the infant getting wedged between the side of the bassinet and an added mattress or pillow. All but two of the 82 decedents were 5 months old or younger in age; one infant was 7 months old and another was 8 months old. There were four fatalities with not enough information to allow the CPSC to determine the hazard scenario.

2. Nonfatal Injuries

A total of 241 bassinet-related, nonfatal incidents were reported from November 2007 through December 2011. Fifty-two of these incidents reported an injury to an infant using the

bassinet or cradle. The majority of the injuries, (30 out of 52), were identified as resulting from falls out of the bassinets. Because 28 of the 30 falls were reported through the emergency department-treated injury surveillance system, little or no circumstantial information is available on how the fall occurred. However, the reports do indicate that 76 percent of the injured infants who fell out of bassinets were older than the ASTM-recommended maximum age limit of 5 months, with four infants as old as 9 months of age falling out of bassinets. All of the falls resulted in head and facial injuries.

Overall, there were six bassinet-related injuries that reportedly required hospitalization. Four of them, all serious head injuries, resulted from a fall out of the bassinet. One injury, a leg fracture, resulted from a caregiver unknowingly attempting to lift an infant out of the bassinet while the infant's leg was caught in a structural opening. The remaining hospitalized injury was due to a moldy bassinet pad that caused respiratory illness to the infant.

Two additional serious injuries were reported, but neither of these infants was hospitalized. There was a report of a second-degree burn suffered by an infant from the bassinet's overheated mobile and a report of an arm fracture from an infant's arm getting caught in the bassinet. The remaining injuries were limited mostly to contusions and abrasions.

The remaining 189 reports either indicated that no injury had occurred or provided no information about any injury. However, many of the descriptions indicated the potential for a serious injury or even death.

3. Hazard Analysis

Based on the incident data, the Commission identified hazard patterns associated with bassinet and cradle incidents. The incidents were grouped into four broad categories:

- Product-related issues;

- Non-product-related issues;
- Recalled product-related issues; and
- Miscellaneous other issues.

1) *Product-related issues:* The hazard scenarios in 209 of the 335 incidents (62 percent) reported were attributed to some sort of failure/defect or a potential design flaw in the product itself. This category includes five fatalities and 46 injuries, five of which involved hospitalization. Listed below are the reported problems, beginning with the most frequently reported concerns:

- Lack of *structural integrity*, which includes issues such as instability, loose hardware, collapse of the product, and loose wheels. This issue was reported in 64 (about 19 percent) of the incidents. One death is associated with this issue.
- Reports of infants *falling or climbing out* of bassinets/cribbs. This category accounted for most of the bassinet-related injury reports that were received from emergency departments around the United States. While little product-/scenario-specific information was available in these reports, a majority indicated that the victims were over the ASTM-recommended upper age limit of 5 months. This issue was reported in 32 (about 10 percent) of the incidents.
- Problems with *mattress flatness* in bassinet attachments to play yards. Examples include mattresses that would not remain level horizontally because of poorly designed metal rods/other structures that are meant to be positioned underneath the mattress; lack of rigid mattress support; and failure of straps/hooks/bars designed to hold the bassinet attachment inside the play yard. This issue was reported in 31 (about 9 percent) of the incidents and was associated with three deaths.

- Problems with ***rocking*** bassinets and cradles, with locking or tilting issues that caused the infant to roll/press up against the side/corner of the product and posed a suffocation hazard. This issue was reported in 23 (about 7 percent) of the incidents, including one death.
- Problems with ***packaging*** of the product that resulted in broken/damaged products during delivery. This issue was reported in 19 (about 6 percent) of the incidents.
- Problems with bassinet ***mobiles***, where components overheated, smoked, or sparked. This issue was reported in 13 (about 4 percent) of the incidents.
- ***Miscellaneous*** other product-related problems, ranging from a tear in the bassinet fabric, to odors, to product assembly/quality issues. Twenty-seven (about 8 percent) of the incidents reported these issues.

2) *Non-product-related issues:* Eighty-three of the 335 reports (25 percent) were about incidents that involved no product defect or failure. This category consisted of 82 fatalities, most of which were associated with the use of soft/extra bedding or prone positioning. There was also one nonfatal injury incident that did not involve any product-related issues.

3) *Recalled product-related issues:* There were 26 reports (8 percent) that involved recalled products. Some of the reports were received by CPSC staff prior to the recalls being published. There were three fatalities and two injuries due to entrapment and/or hanging of an infant between structural components of the bassinet. Most of the remaining reports were complaints or inquiries from consumers regarding a recalled product.

4) *Miscellaneous other issues:* The remaining 17 (5 percent) incident reports were related to miscellaneous other or unspecified issues. Some of these reported concerns from consumers about perceived safety hazards; others described incidents with insufficient specificity for CPSC

staff to identify the hazard scenario. There were four fatalities (unknown circumstances) and three injuries, including a hospitalized injury, reported in this category.

In summary, there are five product-related issues associated with incident deaths and/or significant injuries:

- structural integrity/instability,
- mattress flatness,
- rocking,
- falling or climbing out, and
- entrapment in fabric sided products (recalled product-related).

In addition, there are multiple deaths associated with the use of soft/extra bedding or prone positioning of the child that are considered non-product related.

4. Recalls.

There have been a total of five consumer-level recalls involving bassinets from October 2006 through June 2012.

One recall, involving 46,000 bassinets manufactured from July 2008 through May 2010, pertained to the latching system between the bassinet bed and the frame/stand. The latches that attach the bassinet bed onto the metal frame/stand could appear to be locked in place but still remain unlocked. This allowed the bassinet bed to become detached from the metal frame/stand, causing the bassinet bed to fall and the infant to be injured. There were seven incidents reported to CPSC and the manufacturer. One infant received a bruised cheek when the bassinet bed detached from the metal frame/stand and landed sideways on the floor with the infant inside. (The proposed Removable Bassinet Bed Attachment test, discussed in Sections F and G, would address this hazard.)

Another recall, conducted on February 16, 2011, involved all bassinets manufactured by the company before June 2010. The cross-bracing rails on the bassinet stands were misinstalled, and thus, were not fully locked into position, resulting in the bassinet collapsing, which caused the infant to fall to the floor or fall within the bassinet and suffer injuries. The manufacturer received 10 reports of incidents in which two infants received minor injuries as a result of the collapses, including bruises to the head and shoulder. Consumers were supplied with better instructions and guidance on how to install the cross-braces properly. This was a very design-specific hazard, and CPSC staff has not seen similar incidents from other manufacturers.

The third recall was conducted in December 2009 and involved five models that were bassinet accessories to play yards. This recall involved metal bars used to support the floorboard of the bassinet accessory that came out of the fabric sleeves and created an uneven sleeping surface, posing a risk of suffocation or positional asphyxiation. The manufacturer received no reports of injuries. (The proposed mattress flatness requirement, discussed in Sections F and G, would address this hazard.)

A fourth recall, conducted in May 2009 by the same manufacturer as in the third recall, also involved portable play yards. The convertible play yard included a bassinet accessory and changing station feature and was manufactured before December 1, 2008. This recall involved the play yard's rocking bassinet accessory that was tilting, even when secured by straps in the non-rocking mode, or that stayed tilted without returning to a level sleeping surface while in the rocking mode. These conditions could cause an infant to roll to the corner or side of the bassinet and become wedged in the corner or pressed against the side or bottom of the bassinet, posing a risk of suffocation or positional asphyxiation. The manufacturer and CPSC received 10 reports of infants rolling to one side, including six that had their faces pressed against the side or the

bottom of the bassinet. One child reportedly was turning purple and was out of breath when discovered. No other injuries were reported. (The rock/swing angle test, proposed in the 2010 NPR and added to the ASTM standard in its 2012 iteration, would address this hazard.)

The fifth recall, conducted in September 2008, involved 3-in-1 and 4-in-1 convertible bassinets that contained metal bars covered by an adjustable fabric flap attached with Velcro.[®] The fabric was folded down when the bassinet was converted into a bedside sleeper position. If the Velcro[®] was not resecured properly when the flap is adjusted, an infant could slip through the opening and become entrapped in the metal bars and suffocate. CPSC learned that on August 21, 2008, a 6½-month-old girl died when she became entrapped and strangled between the bassinet's metal bars. This is the second strangulation death that the CPSC learned of involving the co-sleeper bassinets. On September 29, 2007, a 4-month-old girl became entrapped in the metal bars of the bassinet and died. (The fabric-sided openings test, proposed in the 2010 NPR and added to the ASTM standard in its 2012 iteration, would address this hazard.)

E. April 2010 NPR and Subsequent Changes to the ASTM Voluntary Standard

In April 2010, the Commission approved a proposed rule on bassinets/cribels that referenced the requirements specified in ASTM F2194-07a^{e1} as a mandatory standard for bassinets and cribs, with several modifications to further reduce injuries and deaths. The modifications and edits included the following:

- Updated warnings;
- Stability requirements;
- Performance requirements for fabric-sided products to address entrapment incidents;
- Performance requirements to limit the rocking/swinging angle to 20 degrees and the rest angle of certain rocking/swinging cribs to 5 degrees;

- Requirement to eliminate active restraints;
- Changes to scope and terminology; and
- Performance requirements specifying a mattress flatness angle of 5 degrees to address suffocation incidents on segmented mattresses.

The April 2010 NPR also proposed to include hammocks within in the scope of the standard.

Many of the changes proposed in the April 2010 NPR have been incorporated in some capacity into ASTM F2194-12. Other changes to ASTM F 2194-12 have come about in response to comments to the April 2010 NPR. The Commission proposes to revise two of the proposed changes to the 2010 NPR (involving hammocks and the mattress-flatness requirement), based on review of public comments, further testing and analysis, and discussions with the ASTM task group on bassinets.

1. Proposed Changes in April 2010 NPR Incorporated into ASME F2194-12.

Restraints

The 2010 NPR proposed to prohibit bassinets with restraints that require action on the part of the caregiver to secure the restraint. A commenter requested that bassinets be allowed to have restraints and provided several reasons why they should be allowed. The primary reason that the Commission believes restraints should not be allowed in bassinets is that most bassinet uses do not require a restraint, so consumers have a strong motivation to avoid using restraints, if they are provided. When unused, restraints have been known to entrap and strangle children in similar products, like swings, handheld infant carriers, and bouncers. While none of the bassinet incidents was associated with restraint harness strangulation, this is probably due to the fact that restraints are rare on bassinets and not because they would not pose a hazard if they were present.

The 2012 version of F2194 contains a stronger requirement than that proposed in the April 2010 NPR that prohibits *all* restraints in bassinets. The Commission supports this change to the standard, and notes that it is more conservative than the restraints requirement proposed in the 2010 NPR.

The Prominence of Warnings about Soft Bedding

The 2010 NPR proposed a stronger warning label to address suffocation hazards. The current ASTM standard for bassinets, F2194-12, includes an enhancement of the soft bedding warnings by: (1) increasing the font size for the suffocation warning label to 0.4 inches or higher; and (2) adding emphasis by stating that “Infants have suffocated . . .,” rather than stating “Infants can suffocate . . .”

Maximum Rock/Swing and Rest Angles

The Commission’s 2010 NPR proposed a maximum rock/swing angle of 20 degrees and a maximum rest angle of 5 degrees for rocking cradles. Several commenters recommended a maximum rock/swing angle of 20 degrees and a maximum rest angle of 7 degrees for rocking cradles. The 5-degree angle was based on the Australian standard for rocking cradles. In the Australian standard, the angle is measured with the CAMI infant dummy placed in the center of the cradle. The intent is to ensure that the rocking cradle returns to a level position and provides a flat sleeping surface for the infant. In ASTM F2194-12, the angle is measured with the CAMI dummy placed to one side of the cradle. The Commission believes that the placement of the CAMI to one side results in a more stringent requirement than the Australian standard. For this reason, a 7-degree rest angle is a reasonable and achievable requirement for bassinets that will address suffocation hazards associated with an angled sleep surface. Therefore, the Commission is not making any recommendations with respect to this issue.

Fabric-Sided Enclosed Openings Test

The performance requirements for fabric-sided products included in F2194-12 to address entrapment incidents are the same as in the 2010 NPR, except for editorial changes made to clarify the requirement and test procedure.

Stability

The stability requirements are intended to ensure that the product does not tip over when pulled on by a 2-year-old male. The 2010 NPR clarified that the stability requirement applies to all manufacturer-recommended use positions, including the position where the locks are engaged to prevent rocking/swinging motion. ASTM incorporated this change in ASTM F2194-11; therefore, it is included in the latest version, ASTM F2194-12.

2. Changes to ASTM F2194 that arose out of a response to comments received on the April 2010 NPR.

Baby Size Limits

In response to the 2010 NPR, one commenter noted that because “bassinets provide an important tool for parents to monitor premature babies,” a target age range for infant occupants may be necessary to enhance the understanding of the developmental milestones used in the warnings. They also suggested that if there is “a size at which a bassinet becomes unsafe for a baby,” then that factor should be listed in the product’s instructions and warnings.

The 2012 version of the ASTM standard includes a reference to the maximum recommended weight in the FALL HAZARD warning label. The Commission supports this addition to the standard.

Static Load

The static load test is intended to ensure structural integrity even when a child three times the recommended (or 95th percentile) weight uses it. This has been modified following publication of the April 2010 NPR to also test play yard bassinet accessories at all four corners to ensure structural integrity of the product.

Side Height Requirement

This requirement, which is intended to prevent falls, was added to F2194-12 in response to comments to the 2010 NPR. The side height requirement in F2914-12 requires that the bassinet/cradle side height be at least 7 ½ inches from the top of the uncompressed mattress surface.

3. Revisions to proposed changes in 2010 NPR.

Hammocks

The Commission's 2010 NPR proposed to include infant hammocks in the scope of the standard. The voluntary standard for bassinets and cradles does not state explicitly whether infant hammocks are included within the scope of the standard. However, the Juvenile Products Manufacturers Association (JPMA) historically has certified some infant hammocks to the bassinet standard because there was not a separate standard for infant hammocks and other inclined sleep products. Including infant hammocks in the scope would effectively ban most infant hammocks currently on the market because, by their nature, they would be unable to meet the performance criteria in the bassinet standard addressing rest angle, segmented mattress flatness angle, and rock/swing angle.

Several comments were received regarding the inclusion of infant hammocks and other inclined sleeping products in the scope of the 2010 NPR. The comments were universally against such inclusion, asserting that this would effectively ban a product that has utility. The

comments also opined that banning them might increase hazardous sleeping arrangements, causing consumers to resort to a substitute product such as a car seat or makeshift soft bedding to prop up an infant. The Commission agrees that alternative products or makeshift products would present additional hazards if consumers chose to use them instead of cribs, bassinets, or other common juvenile products intended for sleep.

An inclined sleeper differs from a bassinet in that it is intended to have an inclined sleep surface and it conforms to the contour of the occupant. Most hammocks have mattresses that are also inclined in a manner that elevates the head, as well as conforming to the body contours of the infant. They are also intended to allow swinging or bouncing motions. These special features, especially elevating the head, are sometimes intended to help prevent reflux. Features that allow head elevation, swinging, and bouncing motions distinguish these products from common bassinets and cradles, which generally have flat mattresses with solid or fabric-covered framed sides. The Commission believes that a separate standard targeted specifically to these products will more effectively address any hazards associated with them. Due to the significant progress in the development of a separate voluntary standard to address hammocks and inclined sleeping products, the Commission is not including them within the scope of this proposed rule.

Mattress Flatness

In the 2010 NPR, a mattress flatness performance test for all types of bassinets and cradles was included. The performance requirement specified a mattress flatness angle of 5 degrees to address suffocation incidents on mattresses. The mattress flatness performance requirement that the Commission is proposing in this document only applies to segmented mattresses because the CPSC's review of the data showed that only segmented mattresses used in play yards were involved in incidents. In addition, the Commission determined that an angle

of 10 degrees or less would still provide protection; allow for testing variances; and also address design and manufacturability concerns with segmented mattress pads. The Commission's new proposal has additional requirements for two-occupant bassinets. The test method now uses a rigid cylinder to simulate the infant, rather than a soft/deformable CAMI dummy. This change provides more consistent test results. The mattress flatness test is discussed in more detail in Section F.

F. Assessment of ASTM Voluntary Standard and International Standards

The Commission believes that ASTM F2194-12 addresses many of the general hazards associated with durable nursery products, such as lead in paints, sharp edges/sharp points, small parts, wood part splinters, scissoring/shearing/pinching, openings/entrapments, warning labels, and toys. The standard also includes specific requirements for tip stability, unintentional folding of the product, and static load.

From the incident data and hazard patterns associated with bassinets and cradles (as discussed in Section C), the Commission identified six addressable hazards: (1) suffocation due to the addition of soft bedding; (2) suffocation/positional asphyxia due to excess mattress pad angle; (3) entrapments in fabric-sided openings; (4) suffocation due to excess rock/swing angles; (5) misassembly of removable bassinet beds; and (6) falls and climb-outs. Following is an analysis of the adequacy of ASTM F2194-12 in addressing these hazards.

1. Suffocation due to the addition of soft bedding.

The majority of the deaths associated with bassinets and cradles were asphyxiations due to the presence of soft or extra bedding in the bassinet, prone placement of the infant, and/or the infant getting wedged between the side of the bassinet and an added mattress or pillow.

As mentioned in Section E of this preamble, since publication of the 2010 NPR, ASTM F2194 has been revised to strengthen the suffocation warning. Specifically, ASTM F2194-12, includes an enhancement of the soft bedding warnings by: (1) increasing the font size for the suffocation warning label to 0.4 inches or higher; and (2) adding emphasis by stating: “Infants have suffocated . . .,” rather than indicating: “Infants can suffocate...”

The Commission supports the strengthening of the suffocation warning label as included in the latest revision of the ASTM voluntary standard and does not believe that there are additional requirements that can be put in place in the standard to address unsafe sleep environments and unsafe sleep practices. The Commission will continue information and education efforts, such as the Safe Sleep campaign, to address suffocation and other serious sleep hazards.

2. Suffocation/positional asphyxia due to excess mattress pad angle.

Bassinets that are commonly sold as accessories to play yards use the floor of the play yard (a segmented mattress pad) as the floor of the bassinet. Seams between segments of folding play yard bassinet accessory mattress pads have been known to create a valley shape in a bassinet sleeping surface in the crease between adjoining segments of the mattress.

An inclined sleeping surface (on a product not intended to provide a contour or other means to contain the child) can contribute to an infant rolling, increasing the likelihood that they will be found face down and become trapped in a significant V-shaped crease. When lying prone in a valley (or V-shaped crease), infants may have more difficulty keeping their airways unobstructed than they would on a flat surface because their faces are trapped in the juncture between adjacent surfaces. Their heads cannot rotate to the side as much as when the sleeping surface is flat. Immature head control and weak neck muscles may not allow them to free their

airways. Thus, infant sleeping surfaces need to be as firm, flat, and level as possible because soft, uneven and non-level surfaces may create a higher risk of suffocation than a level surface.

The Commission has identified incidents associated with a sleeping surface (segmented mattress) that is not level or flat. The data include fatal and nonfatal incidents involving play yard attachment bassinets with insufficient mattress support.

In one in-depth investigation (IDI), the product was apparently assembled without two key structural support bars beneath the mattress pad of a bassinet accessory that was intended by the manufacturer to be mounted from the top rails of the play yard. The incident summary states:

A 3 month and 26 day old male victim was found deceased inside a play yard. The ME determined that the cause of the death was asphyxia. The victim was found face down in a crease produced by the mattress. He was pronounced deceased at the hospital.

The Commission notes that requirements to ensure that key structural supports are properly installed by consumers would have helped prevent this incident from occurring. The Bassinet Misassembly Provision NPR, published on August 29, 2012, is a Commission-directed NPR to amend the play yard mandatory standard to include a provision to address the hazards associated with play yard bassinet accessories that can be misassembled. (77 FR 52272). However, there has never been a requirement for sleeping surfaces to be flat or even nearly flat, which is the critical feature of the product that constitutes a hazard. A play yard could be designed to position the occupant in a valley, and it would still pass the play yard standard and the misassembly provision. The Commission believes both requirements are necessary to address these hazards: (1) a missing component requirement to prevent installation/use of a bassinet accessory that has a key component missing; and (2) a flatness requirement to ensure segmented mattresses, like

those found in bassinet accessories, are flat when assembled according to manufacturer's instructions.

In another IDI, the victim was in a bassinet accessory to a play yard that was also misassembled. The incident summary states:

A two month old male was found unresponsive in his . . . play yard with no signs of trauma. The child had rolled in the bassinet section causing his face to be placed in the corner of the bassinet. He was lying on a blanket with another blanket on top of him. Investigators who initially measured the bassinet at the scene reported that one side was five inches higher than the other. I observed during my investigation that depending on weight and movement that there will be a variance in height within the unit.

Other risk factors also may have contributed to the incident (e.g., the placement of the infant to sleep in the prone position and the presence of a blanket under the infant), but the case nonetheless illustrates the potential for non-level sleeping surfaces to contribute to bassinet occupants getting into fatal positions from which they may not be able to remove themselves.

A third fatality involved a victim with serious physical challenges who was placed face down to sleep (both of these are additional risk factors) and was found in a sagging bassinet accessory to a play yard. The incident report states:

The mother was using the elevated playpen platform for her 5 month old male baby's sleeping area. He was born with multiple physical complications including the inability to swallow and would drool constantly. The parents placed the infant in the playpen at night face down and awoke to find he had expired in the middle of the night. The playpen elevated platform showed sagging in the center possibly due to incorrect assembly of the playpen.

In the fourth incident involving a fatality, a baby died in the corner of a tilted bassinet accessory on a play yard. A rod intended to be placed in a pocket at the end of the accessory was left out. When a clip on the corner of the bassinet came off for unknown reasons, the sleeping surface tilted downward, allowing the infant's head to become entrapped. While the incident was included in data used for the final rule briefing package for play yards, it is included here because the manner of death is related to a non-level, segmented mattress.

In addition to the fatal incidents, a nonfatal incident was found to be associated with the same hazard. In this incident, a child in a bassinet accessory of a play yard was observed rolling into seams on the sleep surface, but the child was not injured. The incident report states:

No injury occurred to a five-month-old female, who while asleep in the bassinet section of a portable and collapsible play yard rolled into a seam of the removable changing pad used with the bassinet. The mother of the five-month old noticed that the five month old had a tendency to roll into seams of the mattress pad when it was used with the bassinet.

There is no requirement for mattress flatness in ASTM 2194. The 2010 NPR proposed a mattress flatness requirement that specified a 5-degree maximum tilt angle for segmented sleeping surfaces, like those found in play yard bassinet accessories. The ASTM subcommittee for bassinets believed that the 5-degree maximum angle was not achievable within the tolerances necessary to manufacture play yard bassinet accessories; accordingly, they considered alternative test methods and requirements for sleeping surface flatness in products with segmented mattresses.

In lieu of the 5 degrees proposed in the 2010 NPR for segmented mattresses, the ASTM subcommittee sent out to ballot a requirement that allowed up to 14 degrees on either side of a valley formed at a seam, with higher inclines possible if the sum of the two angles on either side

of the valley did not exceed 28 degrees in total. The 14-degree angle was based on an extrapolation of angles formed by dimensions of *average* infant faces. By combining an infant's mandible width with dimensions of nasal protrusion, an isosceles triangle can be created that represents a cross-section of the volume of space beneath the nose. From this cross-section, one can extrapolate both the angle of the valley and the angle of the incline of the surface that would contact a prone infant's face. The angle resulting from the combination of the *average* facial dimensions is 15 degrees, from which the ASTM subcommittee subtracted a single degree for a factor of safety. This ASTM ballot item received many negative votes and was not approved for the standard.

The Commission is uncomfortable using the *average* infant facial dimension as the basis for this requirement. A product that has a 14-degree angle in the valley formed at the seam of the mattress would leave about one-half of the potential occupant population unprotected from suffocation. While the ASTM Committee used an angle resulting from the combination of *average* facial dimensions, the Commission generally recommends using the smallest users' anthropometrics for justifying requirements of this nature. If the facial measurements of the smallest (5th percentile) infants are used to form the isosceles triangle, the resulting valley is 158 degrees, which yields an 11-degree angle of sleep surface incline from the horizontal on each side. If a single degree is subtracted from this incline angle for a minor factor of safety, the requirement becomes a 10-degree maximum incline from the horizontal. In the Commission's proposed test, each seam of a folding bassinet sleeping surface is tested with a pass/fail criterion of 10 degrees maximum for either side of the valley formed by a weighted cylinder.

In August 2012, ASTM reballoted the mattress flatness test. Several modifications were made to the test procedure, and CPSC staff was involved throughout the development of this

requirement. The actual test procedure that was reballotted by ASTM is identical to the Commission's recommendation. However, the test requirement (the pass/fail criteria) is different. In the test procedure, a measurement is taken on each side of each seam of the mattress (for a total of 6 or 8 measurements per bassinet). As mentioned, the Commission is proposing a test requirement of 10 degrees maximum for each measurement taken. Under the ASTM ballot, 10 degrees or less for all measurements would pass, more than 14 degrees for one or more measurements would fail, and any angle measurements between 10 and 14 degrees would require a two-step process where the test lab would take two additional measurements, average them, and then use 10 degrees as the final pass/fail delineator.

With regard to the test method itself, the 2010 NPR's method for testing flatness used a CAMI dummy to weight the surface prior to measuring the side angles of the valley formed in the sleeping surface. However, the CPSC and the ASTM subcommittee prefer a rigid cylinder to help increase the reliability of the test across test laboratories. This is because CAMI dummies tend to vary slightly with age because of the nature of their construction. CPSC staff tested a variety of cylinder diameters and lengths and found that small differences in the footprint of the test cylinder were not critical to differentiating hazardous from nonhazardous products. The most critical factor was the design of the mattress support structure. An exact replica of the human form is not necessary for this type of screening, and the benefits of using standardized, readily available test methods are appreciated by industry. As previously mentioned, the test procedure that the Commission is proposing is identical to what ASTM recently balloted.

3. Entrapments in fabric-sided openings.

Three deaths associated with bassinets and cradles were due to entrapment and/or hanging that resulted after an infant's body, but not head, slipped through the fabric covering and

underlying structural components of a particular brand of convertible bassinets/bedside sleepers of a particular brand of convertible bassinets/bedside sleepers. These incidents occurred in one manufacturer's bassinet that was recalled on August 28, 2008.

As discussed in Section E, since publication of the 2010 NPR, ASTM has revised the bassinet standard to include a fabric-sided enclosed openings test. The test, as added to the 2012 version of the standard, is very close to what was included in the 2010 NPR. Thus, the Commission is not recommending any further changes relating to this hazard.

4. Suffocation due to excess rock/swing angles.

Bassinets and cradles with locking or tilting issues that caused the infant to roll/press up against the side/corner of the product pose a suffocation hazard. There have been several nonfatal incidents and one fatality associated with a rocking bassinet. In the fatal incident, a 1-month-old was found pressed up against the fabric side of a bassinet. It is not known whether the lock, which was designed to prevent rocking, was engaged properly, or wasn't functioning correctly.

As discussed in Section E, since publication of the Commission's 2010 NPR, ASTM has included a rock/swing angle requirement in its standard. The requirement specifies a maximum of 20 degrees for the swing angle and 7 degrees for the rest angle. The Commission believes that this requirement adequately addresses the hazard. Thus, the Commission is not proposing any further changes to the standard relating to this hazard.

5. False latching/stability of removable bassinet beds. The Commission is aware of several incidents involving bassinets beds that were designed to be removed from their stand, four of which have IDIs. During the incidents, the bed portion of the unit was not completely locked or properly attached to its stand. The bed portion of the unit appeared to be stable, giving the

caregivers a false sense of security. For various reasons, the bed portion fell or tilted off of its stand. In one case, a 3-month-old infant was killed. The Commission was also informed by Health Canada of a second death. In e-mail correspondence from Health Canada staff, the following was reported:

It strongly appears the bassinet was not attached to the base when the infant was put down for a nap. When the infant was found, the bassinet was perpendicular to the base and had fallen into the base opening at an angle suspending the infant. The straps and hooks attaching the bassinet to the base were not snapped in.

There have also been nonfatal incidents involving bassinet beds that tipped over or fell off their base/stand when they were not properly locked/latched to their base/stand, or the latch failed to engage as intended. In May 2012, there was a recall of 46,000 bassinets that could appear to latch to the stand when they actually had not latched.

(<http://www.cpsc.gov/cpscpub/prerel/prhtml12/12173.html>).

The reason that removable bassinet designs need inherent stability (or obvious instability) is consumers will sometimes avoid activating lock or latch mechanisms if it appears that the bassinet bed is stable when placed on its stand/base. Consumers may do this because the locks or latches seem redundant or because they are worried about making noise when activating locks or latches around a sleeping infant. Locks and latches also accidentally may give feedback that they are locked when they are not. This constitutes a “false latching” situation. Because of these foreseeable use patterns, this requirement will make bassinets with a removable bed portion inherently stable or have visible indicators to show when the bassinet bed is not properly attached to the stand.

Commission staff has been actively involved in an ASTM task group that is currently developing requirements to address the hazards associated with bassinets with removable bed portions. To date, the language that the task group drafted has yet to be balloted. The Commission proposes adding a new requirement for the NPR, based on what the ASTM task group has developed to date. The proposed requirement allows multiple options to pass. These options will either ensure that the bed portion of the unit is inherently stable when it is placed on the stand unlatched, or it will give obvious feedback that the unit is not latched or stable. One option allows the unit to give an extreme appearance of instability by being tilted 20 degrees or more. The 20-degree minimum is twice the allowable deviation from horizontal that staff recommends for sleeping surface flatness. This angle was extrapolated from an IDI report involving a caregiver who noticed that a bassinet was tilted. From photographs of the incident product, the ASTM task group assigned to examine the problem estimated that the unit produced about a 17-degree angle, which they felt would be reasonable to round up to 20 degrees for the standard. A sleeping surface at 20 degrees from the horizontal seems severe enough that consumers would notice that it was not level. This proposed requirement is slightly less than the angle proposed to address similar hazards in the play yard standard (*i.e.*, 30 degrees from the horizontal), but the ASTM subcommittee reasoned that bassinets are different in structural design and materials and will appear to be misassembled more easily than the suspended and segmented mattress supports used in play yards.

In addition to the aforementioned options, a bassinet that has a removable bed would also pass the requirement if it has a visual indicator to alert a caregiver that the bassinet bed is not properly locked onto the stand. Or, the bassinet would also pass the requirement if it can pass the standard's stability test while in an unlocked position.

6. Falls and Climb-Outs

The majority of the nonfatal injuries (30 out of 52, or 58 percent) were identified as falls from the bassinets. Because 28 of the 30 falls were reported through the emergency department-treated injury surveillance system, little or no information is available on how the falls occurred. However, the reports do indicate that 76 percent of the injured infants who fell out of bassinets were older than the ASTM-recommended maximum age limit of 5 months, with four infants as old as 9 months of age. All of the falls resulted in head and facial injuries.

The Commission believes the new side height requirement in ASTM F2194-12, which requires a bassinet side to be at least 7.5 inches above the mattress surface, as well as the proposed removable bassinet requirements, will help address fall hazards.

In addition to the requirements for mattress flatness and removable bassinet bed attachments, the Commission is proposing changes to the scope of the standard and a revised test method for stability.

Scope.

In order to clarify which products are covered under the scope of the proposed standard and to ensure more complete coverage of sleep products, the Commission is proposing the following with respect to the scope of the ASTM standard. The scope would encompass products with an incline of 10 degrees or less, but not products with a greater than 10-degree angle. This would include cradle swings within the scope, which, by definition, recline less than 10 degrees. The Commission proposes including products that can be supported by a stationary frame/standard, such as carriage attachments to strollers and Moses baskets, only when they are used with a stationary or rocking stand. (A Moses basket is a portable cradle, typically made from wicker or cloth, with no legs or a stand.) Finally, the Commission proposes to specify that

the standard covers products *primarily* used to provide sleeping accommodations. This would expand the scope beyond products *only* used to provide sleeping accommodations. This would ensure, for example, that a bassinet sold with a toy mobile that is meant to entertain an infant who is lying in the bassinet would still fall within the scope of the standard.

Stability Test Dummy.

During evaluations of the test methods for removable bassinet beds, Commission staff made comparisons of the stability of products weighted with the newborn CAMI dummy (7.45 lbs) as opposed to the infant CAMI dummy (17.4 lbs). ASTM F2194-12 contains a stability requirement that uses the heavier infant CAMI dummy. There is no rationale included in the ASTM standard for why the heavier dummy was specified in the stability requirement. Use of the newborn CAMI, which is readily available to test labs and represents the 50th percentile newborn, would result in a more conservative stability test. In addition, bassinets are intended for use with newborns. For these reasons, the Commission is proposing a revised test procedure for bassinet stability, which uses a newborn CAMI instead of an infant CAMI.

International Standards.

The Commission reviewed Canadian, European, and Australian standards for bassinets and/or cradles. Many of the requirements found in the 2012 ASTM standard can also be found in some of these international standards.

The European Standard, EN 1130-1: 1996, “Furniture – Cribs and Cradles for Domestic Use,” has several requirements not found in ASTM F2194-12. Most of these additional requirements address hazards associated with cribs intended for use with older children (in excess of the 5-month recommended maximum age for bassinets). Thus, they are not applicable to bassinets.

The scope of the European Standard, EN 12790-2009, “Child Use and Care Articles - Reclined Cradles,” includes inclined bassinets/criadles, car seat carriers, hammocks, and bouncers. Some of the general requirements could apply, but because the scope of the product is not the same, most of the requirements are not applicable to bassinets.

The Australian/New Zealand standard (AS/NZS 4385:1996) contains requirements for rocking and swinging angles that were used to develop some of the requirements in ASTM F2194. The ASTM rock/swing rest angle performance requirement, while based on AS/NZS 4385:1996, contains a more severe test method than that in AS/NZS 4385:1996, due to the placement of the CAMI dummy. This is discussed more fully in Section E.

The Canadian standard (SOR 86-962: 2010) includes requirements for cribs and non-full-size cribs. This standard does not distinguish between a bassinet and non-full-size cribs. As a result, many of the requirements are not applicable for this NPR. However, the Canadian standard was used to develop the ASTM requirement for bassinet side height.

The Commission believes that the current ASTM F2194-12 standard is the most comprehensive of the standards to address the incident hazards. There are some individual requirements in various foreign standards that are more stringent than ASTM; however, many of these requirements do not address the identified hazards in the incident data reported to the CPSC.

G. Description of Proposed Changes to ASTM Standard

The proposed rule would create a new part 1218 titled, “Safety Standard for Bassinets and Cradles.” The proposal would establish ASTM F2194-12, “Standard Consumer Safety Specification for Bassinets and Cradles,” as a consumer product safety standard, but with certain changes. These proposed changes include a revision to an existing test method (the bassinet

stability test method), two additional new requirements and associated test methods (for mattress flatness and removable bassinet bed attachments), and a revised scope and associated definitions or references to support these additions. They are detailed herein.

1. Clarifying the scope of the standard and associated definitions (Sections 1.3, 3.1.1, and 3.1.2)

The Commission is proposing to revise the scope of ASTM F2194-12 and corresponding terminology to better define which products fall within or outside the scope of the standard. The current text of ASTM F2194-12 provides that the “consumer safety performance specification covers products intended to provide sleeping accommodations only for an infant up to approximately 5 months in age, or when the child begins to push up on hands and knees, whichever comes first.” The Commission is proposing to change the scope and definition of a “bassinet/cradle”—from products meant exclusively for sleeping—to those intended *primarily* for sleeping. This would ensure that a bassinet sold with a toy mobile that is meant to entertain an infant who is lying in the bassinet, for instance, would still fall within the scope of the standard.

The Commission is also proposing to amend the definitions of “bassinet/cradle” and “bassinet/cradle accessories” to specify that the sleeping surface of these products, while in a rest (non-rocking or swinging) position, is intended to be less than or equal to 10 degrees from horizontal. This change would complement the definition of “inclined sleeper” in the draft ASTM inclined sleeper standard, which defines the “inclined sleeper” as having more than a 10-degree sleep surface incline. Thus, the following are covered under the standard: cradle swings with inclines less than or equal to 10 degrees from horizontal while in rest position; carriage baskets/bassinets that are removable from the stroller base, when the carriage basket/bassinet meets the definition of “bassinet/cradle” found in the standard; bassinet/cradle attachments to

cribs or play yards, when in bassinet/cradle-use mode. The following would not fall under the scope of the bassinet/cradle standard: products used in conjunction with an inclined infant swing or stroller and products that are intended to provide an inclined sleep surface (defined as greater than 10 degrees from horizontal while in the rest (non-rocking) position).

2. Segmented Mattress Flatness Requirement and Test Method (Sections 6.9 and 7.10)

In order to address the hazard of suffocation/positional asphyxia due to an excess mattress pad angle, the Commission is recommending performance requirements and a test method for the minimum flatness of segmented mattress surfaces. This requirement applies only to segmented mattresses, such as those seen in a bassinet accessory to a play yard. The Commission recommends that the segmented mattresses commonly used in play yards shall not create an angle greater than 10 degrees when tested using a 17-pound cylinder to simulate the weight of a 6-month-old infant.

3. New Performance Requirement and Associated Definitions to Address Hazards Associated with the Stability of Removable Bassinet Beds (Sections 3.1.3, 3.1.17, 3.1.18, 3.1.19, 3.1.20, 6.10, 7.11)

In order to address hazards associated with misassembly of removable bassinet bed and falls, the Commission is recommending performance requirements and a test method for products that have bassinet beds that attach to an elevated stand. The requirements apply to removable bassinet beds that are designed to separate from the stand/base without the use of tools. The Commission is proposing that if a removable bassinet bed is not properly attached or assembled to its base, it must meet one of the following requirements:

- The base/stand shall not support the bassinet (*i.e.*, the bassinet bed falls from the stand so that it is in contact with the floor); or

- The lock/latch shall automatically engage under the weight of the bassinet bed (without any other force or action); or
- The stand/base shall not be capable of supporting the bassinet bed within 20 degrees of horizontal; or
- The bassinet shall contain a visual indicator mechanism that shall be visible on both sides of the product; or
- The bassinet bed shall not tip over and shall retain the CAMI newborn dummy when subjected to the stability test outlined in the standard.

4. Revised Test Procedure for Bassinet Stability (Sections 2.3 and 7.4.4)

For the reasons described in the previous Section, the Commission is proposing a revised test procedure for bassinet stability that uses a newborn CAMI instead of an infant CAMI.

H. Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of the rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). To allow time for bassinets and cradles to come into compliance, the Commission proposes that the standard would become effective 6 months after publication of a final rule in the *Federal Register*. The Commission invites comment on how long it will take bassinet and cradle manufacturers to come into compliance with the rule.

I. Regulatory Flexibility Act

Introduction

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, requires agencies to consider the impact of proposed rules on small entities, including small businesses. Section 603 of the RFA requires that the Commission prepare an initial regulatory flexibility analysis and make it

available to the public for comment when the notice of proposed rulemaking is published. The initial regulatory flexibility analysis (IRFA) must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the IRFA must contain:

- A description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- A description of the reasons why action by the agency is being considered;
- A succinct statement of the objectives of, and legal basis for, the proposed rule;
- A description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to the requirements, and the type of professional skills necessary for the preparation of reports or records; and
- An identification, to the extent possible, of all relevant federal rules that may duplicate, overlap, or conflict with the proposed rule.

In addition, the IRFA must contain a description of any significant alternatives to the proposed rule that would accomplish the stated objectives of the proposed rule and, at the same time, reduce the economic impact on small businesses.

The Market

Bassinets and cradles are typically produced and/or marketed by juvenile product manufacturers and distributors, or by furniture manufacturers and distributors, some of which have separate divisions for juvenile products. The Commission believes that there are currently at least 55 suppliers of bassinets and/or cradles to the U.S. market; 24 are domestic manufacturers, and 11 are domestic importers. An additional 14 domestic firms have unknown

bassinet/cradle supply sources; three of those firms are retailers and nine specialize in bedding, some of which is sold with bassinets or cradles. There are also six foreign firms supplying the U.S. market: five manufacturers and one importer who imports from foreign companies and distributes from outside of the United States.

Bassinets and cradles from 12 of the 55 firms have been certified as compliant by the JPMA, the major U.S. trade association that represents juvenile product manufacturers and importers. Firms supplying bassinets or cradles would be certified to the ASTM voluntary standard F2194-10, while firms supplying play yards with bassinet/cradle attachments would also have to meet F406-11b. Nine additional firms claim compliance with the relevant ASTM standard for at least some of their bassinets and cradles.

According to a 2005 survey conducted by the American Baby Group (*2006 Baby Products Tracking Study*), 64 percent of new mothers own bassinets; 18 percent own cradles; and 39 percent own play yards with bassinet attachments. Approximately 50 percent of bassinets, 56 percent of cradles, and 18 percent of play yards were handed down or purchased second-hand. Thus, about 50 percent of bassinets, 44 percent of cradles, and 82 percent of play yards were acquired new. This suggests annual sales of about 1.3 million bassinets ($.5 \times .64 \times 4.1$ million births per year); 325,000 cradles ($.44 \times .18 \times 4.1$ million); and 1.3 million play yards with bassinet attachments ($.82 \times .39 \times 4.1$ million). This yields a total of approximately 3 million units sold per year that could be affected by the proposed bassinet/cradle standard.

Reason for Agency Action and Legal Basis for Proposed Rule.

The Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, requires the CPSC to promulgate a mandatory standard for bassinets/cradles that is substantially the same as, or more stringent than, the voluntary standard. CPSC worked closely with ASTM to develop

the new requirements and test procedures that have been added to the voluntary standard since 2010. These new requirements address several known hazard patterns that will help to reduce injuries and deaths in bassinets and cradles, and they have resulted in the current voluntary standard, F2194-12, upon which the proposed rule is based.

However, the Commission proposes adding two new requirements to F2194-12, as well as modifying the scope and the test CAMI dummy used in the existing stability test. The first new requirement would address suffocation and positional asphyxia hazards that have occurred as a result of problems with segmented mattress flatness in play yard bassinet accessories. The second would address the stability of bassinets with removable bassinet beds, particularly the attachment mechanisms. The Commission also proposes modifying the scope (and some of the terminology) to ensure that inclined sleepers (including infant hammocks) would no longer be covered under the bassinet/cradle standard, unless they recline to 10 degrees or less. The expanded scope would also include Moses baskets and stroller carriage accessories when used in conjunction with a stationary stand. These modifications would also help eliminate gaps in product coverage (*i.e.*, most products that may be used for infant sleep will be included under at least one durable nursery product standard). Finally, the Commission proposes that the CAMI newborn dummy be used for stability testing because it more closely resembles the characteristics of bassinet users than the CAMI infant dummy in F2194-12.

4. Requirements of the Proposed Rule

The Commission proposes adopting the voluntary ASTM standard for bassinets and cradles (F2194-12) with a new mattress flatness requirement, a new stability requirement for bassinets with removable beds, a revised scope, and a modified CAMI dummy for the existing stability requirement. Some of the more significant requirements of the current voluntary standard for

bassinets and cradles (ASTM F2194-12) are listed below. The requirements that were added to the ASTM voluntary standard or modified since the 2010 NPR are italicized.

- Spacing of rigid-side components—intended to prevent child entrapment between both uniformly and non-uniformly spaced components, such as slats. *This has been modified for clarity to remove duplicative test references.*
- Openings for mesh/fabric—intended to prevent the entrapment of children’s fingers and toes, as well as button ensnarement.
- Static load test—intended to ensure structural integrity even when a child three times the recommended (or 95th percentile) weight uses it. *This has been modified to also test play yard bassinets in all four corners.*
- Stability requirements—intended to ensure that the product does not tip over when pulled on by a 2-year-old male. *ASTM adopted the revised test requirements included in the 2010 NPR (includes testing with locks/latches engaged).*
- Sleeping pad thickness and dimensions—intended to minimize gaps and the possibility of suffocation due to excessive padding. *F2194-12 allows thicker mattresses for rigid-sided products because a thicker mattress does not pose the same suffocation hazard when used in rigid-sided, rather than soft-sided, products.*
- Tests of locking and latching mechanisms—these are intended to prevent unintentional folding while in use.
- Suffocation warning label—intended to help prevent soft bedding incidents. *F2194-12 requires the warning to use a larger font than the 2010 NPR.*
- *Fabric-sided openings test—intended to prevent entrapments. This test was included in the 2010 NPR and has been adopted in F2194-12 with a few editorial changes.*

- *Rock/swing angle requirement—intended to address suffocation hazards that can occur when latch/lock problems and excessive rocking or swinging angles press children into the side of the bassinet/cradle. The 2010 NPR recommended a maximum rocking angle of 20 degrees and a maximum rest angle of 5 degrees. ASTM F2194-12 adopts the maximum deflection angle of 20 degrees, but includes a maximum rest angle of 7 degrees with a more severe test condition where the CAMI doll is positioned at the side, rather than the center, of the bassinet/cradle.*
- *Occupant restraints—intended to prevent incidents where unused restraints have entrapped and strangled children. The 2010 NPR proposed that only passive restraints be allowed. ASTM F2194-12 is even stricter, allowing no restraints to be used in a bassinet/cradle configuration.*
- *Side height requirement—intended to prevent falls. This requirement, which is new to F2194-12, arose from the comments to the 2010 NPR. A bassinet/cradle side height of 7½ inches from the top of the uncompressed mattress is now required.*

The voluntary standard also includes: (1) torque and tension tests to ensure that components cannot be removed; (2) requirements for several bassinet/cradle features to prevent entrapment and cuts (minimum and maximum opening size, small parts, hazardous sharp edges or points, and edges that can scissor, shear, or pinch); (3) requirements for the permanency and adhesion of labels; (4) requirements for instructional literature; and (5) corner post extension requirements intended to prevent pacifier cords, ribbons, necklaces, or clothing that a child may be wearing from catching on a projection.

The Commission proposes modifying the scope, using the more appropriate infant CAMI dummy for stability testing, and adding new mattress flatness and attachment of removable

bassinet bed requirements to ASTM F2194-12. As part of these changes, there would also be several new or revised definitions, including “bassinet/cradle,” “bassinet/cradle accessory,” and “bassinet bed.” Following is a discussion of the impact of each of these changes.

a. Scope.

There are three major proposed changes to the scope of the bassinet/cradle standard:

1. Specification that it is to cover products primarily used to provide sleeping accommodations. This expands the scope beyond products only used to provide sleeping accommodations.
2. Products with an incline of 10 degrees or less would be included, while products with a greater than 10 degree incline would not. ASTM and CPSC have developed this demarcation across product standards to help ensure complete coverage of sleep products. This would include cradle swings which, by definition, recline less than 10 degrees from horizontal.
3. Specification that it includes products that can be supported by a stationary frame/stand. This would bring in carriage attachments to strollers and Moses baskets *only* when used with a stationary or rocking stand.

These scope changes may affect suppliers in several ways. First, they would provide additional clarity to suppliers regarding which products would be covered under what standards. Reduced confusion means less time reviewing, testing, and making necessary modifications. Second, “cradle swings,” defined by the infant swings standard, F2088-11a, as an infant swing intended for use by a child lying flat (*i.e.*, horizontal), would be covered under both the bassinet standard and the infant swings standard. The Commission believes that cradle swings currently on the market should be able to meet the proposed standard for bassinets without additional

modifications. Third, Moses baskets and carriage attachments to strollers would now be subject to the bassinet/cradle standard when used in conjunction with a separate stand. However, this would apply only to Moses baskets and carriages that are produced and sold by the same company that makes the stand, and therefore, are intended to be used together. Firms that supply bassinet/cradle stands, as well as either Moses baskets or carriage attachments for strollers, would need to ensure that their Moses baskets and/or carriage attachments meet the bassinet/cradle standard when attached to the stand(s). This would likely require some redesign, most notably to meet the side height and stability requirements, and it would affect 10 known firms. Alternatively, they could stop supplying the stands.

b. Stability Testing with Newborn CAMI Dummy

Because bassinets and cradles are intended to be used by very young children, it is appropriate that the smaller newborn CAMI dummy be used for stability testing. The heavier (17.5 pound) infant CAMI currently used for stability testing in F2194-12 could make these products more stable when tested than they actually would be in a real-world situation. Based on preliminary Commission testing, it appears that most bassinet/cradles will be able to pass this revised test procedure without modification. However, at least one product failed stability testing with the newborn CAMI and passed with the infant CAMI. It is possible that a few products may require modifications to meet the revised stability test procedure. It is likely to affect only a few manufacturers, but it is unlikely to require product redesign. Affected firms would most likely increase the stability of their product by widening the structure, making the bassinet bed deeper, or making the base heavier. If meeting the modified requirement necessitates a change to the hard tools used to manufacture the bassinet, the cost could be more significant.

c. Mattress Flatness

The Commission is proposing the addition of a mattress flatness requirement and test method to the standard, as well. The mattress flatness requirement is primarily aimed at incidents involving bassinet/play yard combination products that tend to use segmented mattresses. These incidents suggest that products with mattresses that have multiple seams could pose a suffocation hazard. Based on Commission testing, it appears that the play yard bassinet attachments of many suppliers (both compliant and noncompliant with F2194-10) would pass this requirement without any modifications. Those that do require modifications would need to increase the mattress support in their bassinets. This could be accomplished, for example, by retrofitting their play yard bassinets to use longer rods or a better-fitting mattress shell. The cost of such a retrofit is unknown and would likely vary from product to product; however, it should be less expensive than a product redesign. Based on this information, it appears that at least a few play yard bassinets may require modifications, which could include product redesign. However, it is believed that most firms would opt for the less expensive option of retrofitting their existing designs.

d. Removable Bassinet Beds

Finally, the Commission proposes adding a new requirement and test method to address the attachment of removable bassinet beds. There are several manufacturers with bassinet designs that allow for the bassinet bed to be removed from the stand easily (*i.e.*, without the use of tools) and used separately. In many cases, the bassinet bed sits securely on the stand without any attachment mechanism. In other cases, clips or locks may be used to ensure that the stand retains the bassinet bed during use. Incidents have arisen where the attachments have either failed or have not been used, rendering the bassinet bed unstable. Therefore, CPSC, in conjunction with

an ASTM task group, has developed a requirement and test methods to address the potential instability of some removable bassinet beds when used with a stand.

There are several firms supplying bassinets with removable bassinet beds to the U.S. market. The majority will not need modifications to meet the proposed requirement. However, at least four firms will need to make changes to one or more of their bassinets. Essentially, the products will need to be modified so that they are either inherently stable (automatically lock or stable even without the locks) or obviously unstable (unsupportable or obviously tilted without locks or a visual indicator that locks not in use). There are numerous ways that firms could meet this new requirement if their product(s) required modification, including redesigning the product entirely. However, it seems likely that many firms would opt for less expensive alternatives, such as more sensitive locks that activate with little pressure (*i.e.*, with just the weight of the bassinet).

Other Federal or State Rules

The Commission is in the process of implementing sections 14(a)(2) and 14(i)(2) of the Consumer Product Safety Act (CPSA), as amended by the CPSIA. Section 14(a)(2) of the CPSA requires every manufacturer of a children's product that is subject to a children's product safety rule to certify, based on third party testing, that the product complies with all applicable safety rules. Section 14(i)(2) of the CPSA requires the Commission to establish protocols and standards (i) for ensuring that a children's product is tested periodically and when there has been a material change in the product, (ii) for the testing of representative samples to ensure continued compliance, (iii) for verifying that a product tested by a conformity assessment body complies with applicable safety rules, and (iv) for safeguarding against the exercise of undue influence on a conformity assessment body by a manufacturer or private labeler.

Because bassinets/cribbs will be subject to a mandatory standard, they will also be subject to the third party testing requirements of section 14(a)(2) of the CPSA when the mandatory standard and the notice of requirements become effective.

Impact on Small Businesses

There are approximately 55 firms currently known to be marketing bassinets and/or cribs in the United States. Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of bassinets or cribs is small if it has 500 or fewer employees, and importers and wholesalers are considered small if they have 100 or fewer employees. Based on these guidelines, 38 are small firms—19 domestic manufacturers, 8 domestic importers, and 11 firms with unknown supply sources (including 9 specializing in bedding). The remaining firms are five large domestic manufacturers, three large domestic importers, three large retailers with unknown supply sources, and six foreign firms. There may be additional unknown small bassinet/crib suppliers operating in the U.S. market.

Small manufacturers. The expected impact of the proposed standard on small manufacturers will differ based on whether their bassinets/cribbs are already compliant with F2194-10. Firms whose bassinets and cribs meet the requirements of F2194-10 are likely to continue to comply with the voluntary standard as new versions are published. In addition, they are likely to meet any new standard within 6 months because this is the amount of time JPMA allows for products in their certification program to shift to a new standard. Many of these firms are active in the ASTM standard development process, and compliance with the voluntary standard is part of an established business practice. Therefore, it is likely that firms supplying bassinets and cribs that comply with ASTM F2194-10 (which went into effect for JPMA certification purposes in

November 2010) would also likely comply with F2194-12 by January 2013, even in the absence of a mandatory standard.

It is possible that the direct impact for manufacturers whose products are likely to meet the requirements of ASTM F2194-12 (10 of 19 firms) could be significant for one or more firms if they must redesign their bassinets to meet the proposed rule. While none of these manufacturers would be newly covered due to the proposed change in scope, seven would be affected by the mattress flatness requirement (*i.e.*, they produce play yards with bassinet attachments), and at least two (and possibly four) may be affected by the removable bassinet bed stability requirement. For the most part, the bassinets/cradles and bassinet cradle attachments supplied by these firms will be able to meet the staff-recommended changes to ASTM F2194-12, without modification. In cases where modifications are necessary, they would most likely opt to retrofit their products, rather than undertake an expensive redesign. However, it is possible that some products may require redesign, particularly to meet the new removable bassinet bed stability requirement; therefore, costs could be significant in some cases.

Meeting ASTM F2194-12's requirements could necessitate product redesign for at least some bassinets/cradles that are believed not to be compliant with F2194-10 (9 of 19 firms). Two of these firms produce either Moses baskets or carriage stroller attachments along with separate stands, and therefore, they are included only because of the proposed change in scope. (Since no Moses baskets or carriage attachments for strollers are currently tested to the ASTM bassinets/cradles standard, it is assumed that none would meet ASTM F2194-12 without modifications). The remaining seven firms could require redesign, regardless of the staff-recommended modifications. A redesign would be minor if most of the changes involve adding straps and fasteners or using different mesh or fabric, but it could be more significant if changes

to the frame are required, including changes to side height. One manufacturer estimated that a complete play yard redesign, including engineering time, prototype development, tooling, and other incidental costs, would cost approximately \$500,000. The Commission believes that a bassinet redesign would tend to be comparable. Consequently, the proposed rule could potentially have a significant direct impact on small manufacturers whose products do not conform to F2194-10. However, any direct impact might be mitigated if costs are treated as new product expenses that can be amortized.

It is possible that some firms supply bassinets/cradles that are compliant with F2194-10, even though they are not certified or marketed as compliant. The Commission has identified many such cases with other products. To the extent that some of these firms may supply compliant bassinets/cradles and have developed a pattern of compliance with the voluntary standard, the direct impact of the proposed standard will be less significant than described above. There are also two small firms with unknown supply sources, none of which appear to comply with F2194-10 (one is covered by the proposed rule due to the expanded scope). If these firms are manufacturers, they may also require redesign to meet the proposed standard.

In addition to the direct impact of the proposed standard described above, there are indirect impacts. These impacts are considered indirect because they do not arise directly as a consequence of the bassinet/cradle rule's requirements. Nonetheless, they could be significant. Once the rule becomes final and the notice of requirements is in effect, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements. This will include any physical and mechanical test requirements specified in the final rule; lead and phthalates testing is already required, and hence, not included here.¹

¹ Bassinet and cradle suppliers already must third party test their products to the lead and phthalate requirements. Therefore, these costs are left out of the analysis above.

One manufacturer estimated that testing to the ASTM voluntary standard runs around \$1,000 per model sample, although they noted that the costs could be lower for some models where the primary difference is fabric rather than structure. Testing overseas could potentially reduce some testing costs, but this may not always be practical.

On average, each small domestic manufacturer supplies eight different models of bassinets/cribbs and/or play yards with bassinet/cribb accessories to the U.S. market annually. Therefore, if third party testing were conducted every year on a single sample for each model, third party testing costs for each manufacturer would be about \$8,000 annually. Based on a review of firm revenues, the impact of third party testing to ASTM F2194-12 is unlikely to be significant if only one bassinet/cribb sample per model is required. However, if more than one sample would be needed to meet the testing requirements, third party testing costs could have a significant impact on a few of the small manufacturers.

Small Importers.

As with manufacturers of compliant bassinets/cribbs, the four small importers of bassinets/cribbs currently in compliance with F2194-10 could experience significant direct impacts as a result of the proposed rule, if product redesign is necessary. In the absence of regulation, these firms would likely continue to comply with the voluntary standard as it evolves and likely the final mandatory standard as well. Any increase in production costs experienced by their suppliers may be passed on to them.

Importers of bassinets/cribbs would need to find an alternate source if their existing supplier does not come into compliance with the requirements of the proposed rule, which may be the case with the four importers of bassinets/cribbs believed not to be in compliance with F2194-10 (two of which are covered by the proposed rule due to the expanded scope). Some could respond

to the rule by discontinuing the import of their noncompliant bassinets/cribs, possibly discontinuing the product line altogether. However, the impact of such a decision could be mitigated by replacing the noncompliant bassinets/cribs with compliant bassinets/cribs. Deciding to import an alternative product would be a reasonable and realistic way to offset any lost revenue.

As is the case with manufacturers, all importers will be subject to third party testing and certification requirements, and consequently, they will experience costs similar to those for manufacturers if their supplying foreign firm(s) does not perform third party testing. The resulting costs could have a significant impact on a few small importers who must perform the testing themselves if more than one sample per model were required.

Bedding Suppliers. There are nine known small firms specializing in the supply of bedding, including bedding for bassinets and cribs. Each firm sells basic bassinet or crib shells, covered with their bassinet and crib bedding. While it is clear that these firms do not manufacture the structural parts of the bassinets or cribs themselves, it is unclear whether they purchase them domestically or overseas. Regardless, these firms will be affected by the - proposed rule in a manner similar to importers.

Because none of these firms is believed to supply bassinets or cribs in compliance with F2194-10, they would need to find an alternate source if their existing supplier does not come into compliance with the requirements of the proposed rule. Unlike most importers, however, they would not have the option of replacing a noncompliant bassinet/crib with another product. While they could opt to sell the bedding without the associated bassinet/crib, this is the standard method of sale, and it might make it more difficult to compete in the bassinet/crib market.

As with manufacturers and importers, these firms will also be subject to third party testing and certification requirements, and they will experience costs similar to those for manufacturers if their supplying firm(s) does not perform third party testing. The resulting costs could have a significant impact on some of these small bassinet/cradle suppliers who must perform the testing themselves.

Alternatives

Under the Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, one alternative that would reduce the impact on small entities is to make the voluntary standard mandatory with no modifications. Doing so would eliminate the impact on the six small firms that would be newly covered under the bassinet/cradle standard due to the proposed change in scope. These firms all supply Moses baskets or carriages, along with stationary stands; the Commission believes that these products require additional safety features when used for sleeping purposes. Adopting the voluntary standard without modifications could also reduce the impact on other small manufacturers and importers whose ASTM-compliant bassinets/cradles would require modifications due to the proposed changes. However, because of the severity of the incidents associated with instability and mattress tilt, the Commission does not recommend this alternative.

A second alternative would be to set an effective date later than the proposed 6 months that is generally considered sufficient time for suppliers to come into compliance with a proposed rule. Setting a later effective date would allow suppliers additional time to modify and/or develop compliant bassinets/cradles and spread the associated costs over a longer period of time.

The Commission invites comments describing the possible impact of this rule on manufacturers and importers, as well as comments containing other information describing how this rule will affect small businesses.

J. Environmental Considerations

The Commission’s regulations address whether we are required to prepare an environmental assessment or an environmental impact statement. If our rule has “little or no potential for affecting the human environment” it will be categorically exempted from this requirement. 16 CFR 1021.5(c)(1). The proposed rule falls within the categorical exemption.

K. Paperwork Reduction Act

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). In this document, pursuant to 44 U.S.C. 3507(a)(1)(D), we set forth:

- a title for the collection of information;
- a summary of the collection of information;
- a brief description of the need for the information and the proposed use of the information;
- a description of the likely respondents and proposed frequency of response to the collection of information;
- an estimate of the burden that shall result from the collection of information; and
- notice that comments may be submitted to the OMB.

Title: Safety Standard for Bassinets and Cradles

Description: The proposed rule would require each bassinet and cradle to comply with ASTM F 2194-12, “Standard Consumer Safety Specification for Bassinets and Cradles.” Sections 8 and 9 of ASTM F 2194-12 contain requirements for marking, labeling, and instructional literature. These requirements fall within the definition of “collection of information,” as defined in 44 U.S.C. 3502(3).

Description of Respondents: Persons who manufacture or import bassinets/cradles.

Estimated Burden: We estimate the burden of this collection of information as follows:

Table 1 – Estimated Annual Reporting Burden

16 CFR Section	Number of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Burden Hours
1218	55	5	275	1	275

Our estimates are based on the following:

Section 8.1.1 of ASTM F 2194-12 requires that the name of the manufacturer, distributor, or seller and either the place of business (city, state, and mailing address, including zip code) or telephone number, or both, be marked clearly and legibly on each product and its retail package. Section 8.1.2 of ASTM F 2194-12 requires a code mark or other means that identifies the date (month and year, at a minimum) of manufacture.

There are 55 known entities supplying bassinets to the U.S. market. All 55 firms are assumed to use labels already on both their products and their packaging, but they might need to make some modifications to their existing labels. The estimated time required to make these modifications is about 1 hour per model. Each entity supplies an average of eight different models of bassinets; therefore, the estimated burden associated with labels is 1 hour per model x 55 entities x 5 models per entity = 275 hours. We estimate the hourly compensation for the time

required to create and update labels is \$27.55 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” March 2012, Table 9, total compensation for all sales and office workers in goods-producing private industries: <http://www.bls.gov/ncs/>). Therefore, the estimated annual cost to industry associated with the labeling requirements is \$7,576.25 (\$27.55 per hour x 275 hours = \$7,576.25). There are no operating, maintenance, or capital costs associated with the collection.

Section 9.1 of ASTM F2194-12 requires instructions to be supplied with the product. Bassinets and cradles are products that generally require assembly, and products sold without such information would not be able to compete successfully with products supplying this information. Under the OMB’s regulations (5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the “normal course of their activities” are excluded from a burden estimate, where an agency demonstrates that the disclosure activities required to comply are “usual and customary.” Therefore, because we are unaware of bassinets or cradles that generally require some installation, but lack any instructions to the user about such installation, we tentatively estimate that there are no burden hours associated with section 9.1 of ASTM F2194-12 because any burden associated with supplying instructions with bassinets and cradles would be “usual and customary” and not within the definition of “burden” under the OMB’s regulations.

Based on this analysis, the proposed standard for bassinets would impose a burden to industry of 275 hours at a cost of \$7,576.25 annually.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. § 3507(d)), we have submitted the information collection requirements of this rule to the OMB for review. Interested persons are requested to submit comments regarding information collection by

[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], to the Office of Information and Regulatory Affairs, OMB (see the **ADDRESSES** section at the beginning of this notice).

Pursuant to 44 U.S.C. 3506(c)(2)(A), we invite comments on:

- whether the collection of information is necessary for the proper performance of the CPSC’s functions, including whether the information will have practical utility;
- the accuracy of the CPSC’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- ways to enhance the quality, utility, and clarity of the information to be collected;
- ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology; and
- the estimated burden hours associated with label modification, including any alternative estimates.

L. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury, unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as “consumer product safety rules,” thus implying that the preemptive effect of section 26(a) of the CPSA would apply. Therefore, a rule

issued under section 104 of the CPSIA will invoke the preemptive effect of section 26(a) of the CPSA when it becomes effective.

M. Certification and Notice of Requirements (NOR)

Section 14(a) of the CPSA imposes the requirement that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Section 14(a)(2) of the CPSA requires that certification of children's products subject to a children's product safety rule be based on testing conducted by a CPSC-accepted third party conformity assessment body. Section 14(a)(3) of the CPSA requires the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformity assessment bodies (or laboratories) to assess conformity with a children's product safety rule to which a children's product is subject. The proposed rule for 16 CFR part 1218, "Safety Standard for Bassinets and Cradles," when issued as a final rule, will be a children's product safety rule that requires the issuance of an NOR.

On May 24, 2012, the Commission published in the *Federal Register* the proposed rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 77 FR 331086, which, when finalized, would establish the general requirements and criteria concerning testing laboratories. These include the requirements and procedures for CPSC acceptance of the accreditation of a laboratory to test children's products in support of the certification required by section 14(a)(2) of the CPSA. The proposed rule at 16 CFR part 1112, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, lists the children's product safety rules for which the CPSC has published NORs for laboratories. In this document, the Commission is proposing to amend the list in 16 CFR part 1112, once that rule becomes final, to include the bassinet

standard, once finalized, along with the other children's product safety rules for which the CPSC has issued NORs.

Laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the new standard for bassinets and cradles would be required to meet the third party conformity assessment body accreditation requirements in 16 CFR part 1112, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, once that rule becomes final. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body it can apply to the CPSC to have 16 CFR part 1218, Safety Standard for Bassinets and Cradles included in its scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC website at www.cpsc.gov/labsearch.

The final NOR will base the CPSC laboratory accreditation requirements on the performance standard set forth in the final rule for the safety standard for bassinets and cradles and the test methods incorporated within that standard. The Commission may recognize limited circumstances in which the Commission will accept certification based on product testing conducted before the Commission's acceptance of accreditation of laboratories for testing bassinets and cradles (also known as retrospective testing) in the final NOR. The Commission seeks comments on any issues regarding the testing requirements of the proposed rule for bassinets and cradles and the accompanying proposed NOR.

N. Request for Comments

This proposed rule is part of a rulemaking proceeding under section 104(b) of the CPSIA to issue a consumer product safety standard for bassinets and cradles. We invite all interested persons to submit comments on any aspect of the proposed rule. In particular, the Commission invites comments regarding the reliability of proposed 16 CFR 1218.2(b)(7)(ii)(C) (allowing the

option of making the sleep surface of the bassinet bed at least 20 degrees off from a horizontal plane when the bassinet bed is in an unlocked position as a means of meeting the stability requirement) with respect to notifying consumers that the bassinet bed is dangerously unstable as opposed to intentionally designed to rest at an angle. Comments should be submitted in accordance with the instructions in the **ADDRESSES** section at the beginning of this notice.

List of Subjects

16 CFR Part 1112

Administrative practice and procedure, Audit, Consumer protection, Reporting and recordkeeping requirements, Third party conformity assessment body.

16 CFR Part 1218

Consumer protection, Imports, Incorporation by reference, Infants and Children, Labeling, Law Enforcement, and Toys.

For the reasons discussed in the preamble, the Commission proposes to amend Title 16 of the Code of Federal Regulations Chapter II as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

1. The authority citation for part 1112 continues to read as follows:

Authority: Pub. L. 110-314, section 3, 122 Stat. 3016, 3017 (2008); 15 U.S.C. 2063.

2. In §.1112.15, add paragraph (b)(33) to read as follows:

§1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule and/or test method?

* * * * *

(b) * * *

(33) 16 CFR part 1218, Safety Standard for Bassinets and Cradles.

3. Add part 1218 to read as follows:

PART 1218-SAFETY STANDARD FOR BASSINETS AND CRADLES

Sec.

1218.1 Scope.

1218.2 Requirements for bassinets and cradles.

Authority: The Consumer Product Safety Improvement Act of 2008, Pub. L. 110-314, section 104, 122 Stat. 3016 (August 14, 2008).

§ 1218.1 Scope.

This part establishes a consumer product safety standard for bassinets and cradles.

§ 1218.2 Requirements for bassinets and cradles.

(a) Except as provided in paragraph (b) of this section, each bassinet and cradle must comply with all applicable provisions of ASTM F 2194-12, Standard Consumer Safety Specification for Bassinets and Cradles, approved on June 1, 2012. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; <http://www.astm.org/cpsc.htm>. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) Comply with the ASTM F 2194-12 standard with the following additions or exclusions:

(1) Instead of complying with section 1.3 of ASTM F 2194-12, comply with the following:

(i) 1.3 This consumer safety performance specification covers products primarily intended to provide sleeping accommodations for an infant up to approximately 5 months in age, or when the child begins to push up on hands and knees, whichever comes first. Products used in conjunction with an inclined infant swing or stroller, or products that are intended to provide an inclined sleep surface (head-to-toe direction) of greater than 10° from horizontal, while in the rest (non-rocking) position, are not covered by this specification.

Note to Paragraph(b)(1)(i): Cradle swings, with an incline less than or equal to 10° from horizontal while in the rest (non-rocking) position, are covered under the scope of this standard. A sleep product that has an inclined sleeping surface (intended to be greater than 10° from horizontal while in the rest (non-rocking) position) does not fall under the scope of this standard. Strollers that have a carriage/bassinet feature are covered by the stroller/carriage standard when in the stroller use mode. Carriage baskets/bassinets that are removable from the stroller base are covered under the scope of this standard when the carriage basket/bassinet meets the definition of a bassinet/cradle found in 3.1.1. Bassinet/cradle attachments to cribs or play yards, as defined in 3.1.2 or 3.1.12, are included in the scope of the standard when in the bassinet/cradle use mode.

(ii) [Reserved]

(2) Add “CAMI Newborn Dummy (see Fig. 1A). Drawing numbers 126-0000 through 126-0015 (sheets 1 through 3), 126-0017 through 126—0027, a parts list entitled “Parts List for CAMI Newborn Dummy,” and a construction manual entitled “Construction of the Newborn

Infant Dummy” (July 1992). Copies of the materials may be inspected at NHTSA’s Docket Section, 400 Seventh Street, S.W., Room 5109, Washington DC, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.” to “2.3 Other References” and use the following figure:

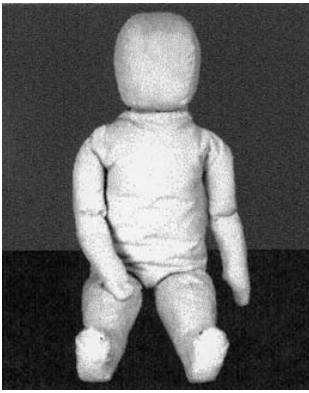


FIG. 1A CAMI Newborn Dummy

(3) Instead of complying with section 3.1.1 of ASTM F 2194-12, comply with the following:

(i) 3.1.1 *Bassinet/cradle*, n – small bed designed primarily to provide sleeping accommodations for infants, supported by free-standing legs, a stationary frame/stand, a wheeled base, a rocking base, or which can swing relative to a stationary base; while in a rest (non-rocking or swinging) position, a bassinet/cradle is intended to have a sleep surface less than or equal to 10° from horizontal.

(ii) [Reserved]

(4) Instead of complying with section 3.1.2 of ASTM F 2194-12, comply with the following:

(i) *Bassinet/cradle accessory*, n –a supported sleep surface that attaches to a crib or play yard designed to convert the product into a bassinet/cradle intended to have a sleep surface less than or equal to 10° from horizontal while in a rest (non-rocking or swinging) position.

(ii) [Reserved]

(5) Instead of complying with section 3.1.3 of ASTM F 2194-12, comply with the following:

(i) 3.1. 3 *conspicuous*, *adj*—describes a label or indicator that is visible, when the bassinet/cradle is in a manufacturer’s recommended use position, to a person standing near the bassinet/cradle at any one position around the bassinet/cradle but not necessarily visible from all other positions.

(ii) [Reserved]

(6) In addition to complying with section 3.1.16 of ASTM F 2194-12, comply with the following:

(i) 3.1.17 *bassinet bed*, n – the sleeping area of the bassinet, containing the sleep surface and side walls.

(ii) 3.1.18 *removable bassinet bed*, n – A bassinet bed that is designed to separate from the base/stand without the use of tools.

(iii) 3.1.19 *false lock/latch visual indicator*, n – a warning system, using contrasting bright colors, lights, or other similar means designed to visually alert caregivers when a removable bassinet bed is not properly locked onto its stand/base.

(iv) 3.1.20 *intended use orientation*, n – The bassinet bed orientation (*i.e.*, the position where the head and foot ends of the bassinet bed are located), with respect to the base/stand, as recommended by the manufacturer for intended use.

(7) In addition to complying with section 6.8 of ASTM F 2194-12, comply with the following:

(i) 6.9 *Segmented Mattress Flatness*—If the bassinet or bassinet accessory has a folding and/or segmented mattress, any angle when measured in section 7.10 shall be less than or equal to 10 degrees.

(ii) 6.10 *Removable Bassinet Bed Attachment* - Any product containing a removable bassinet bed with a latching or locking device intended to secure the bassinet bed to the stand/base, shall comply with 6.10.1, 6.10.2, 6.10.3, 6.10.4 or 6.10.5 when tested in accordance with 7.11.

(A) 6.10.1 The base/stand shall not support the bassinet bed (*i.e.*, the bassinet bed collapses from the stand and contacts the floor).

(B) 6.10.2 The lock/latch shall automatically engage under the weight of the bassinet bed (without any other force or action).

(C) 6.10.3 The sleep surface of the bassinet bed shall be at least 20° off from a horizontal plane when the bassinet bed is in an unlocked position.

(D) 6.10.4 The bassinet shall provide a false latch/lock visual indicator(s) that is conspicuous, at a minimum, on the two longest sides of the product.

(E) 6.10.5 The bassinet bed shall not tip over and shall retain the CAMI newborn dummy.

(8) Instead of complying with section 7.4.4 of ASTM F 2194-12, comply with the following:

(i) 7.4.4 Place the CAMI Newborn Dummy on the sleeping pad in the center of the product face up with the arms and legs straightened.

(A) *Rationale*. The newborn CAMI dummy represents a 50th percentile newborn infant, which is a more appropriate user of a bassinet than the CAMI infant dummy, which represents a 50th percentile 6-month-old infant.

(B) [Reserved]

(ii) [Reserved]

(9) In addition to complying with section 7.9 of ASTM F 2194-12, comply with the following:

(i) 7.10 *Segmented Mattress Flatness Test*.

(A) 7.10.1 Angle measurement for bassinets intended for a single occupant.

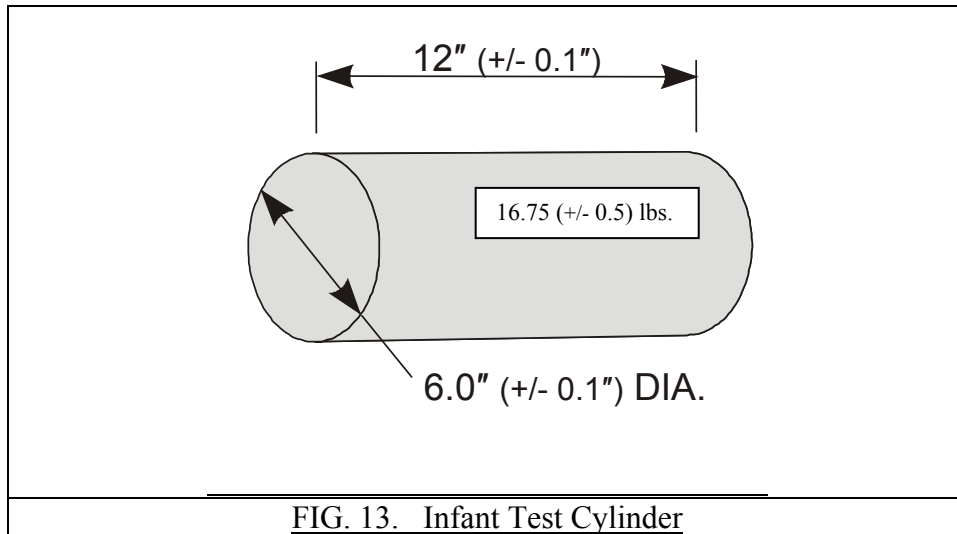
(B) 7.10.1.1 Establish a horizontal reference plane by placing an inclinometer, with an accuracy capable of 0.5° minimum resolution, on the floor of the testing area and zeroing it.

(C) 7.10.1.2 Assemble the product according to the manufacturer's instructions. If the product has more than one mode, assemble in the bassinet mode(s). Disable the rocking/swinging feature if the product is equipped with such a feature.

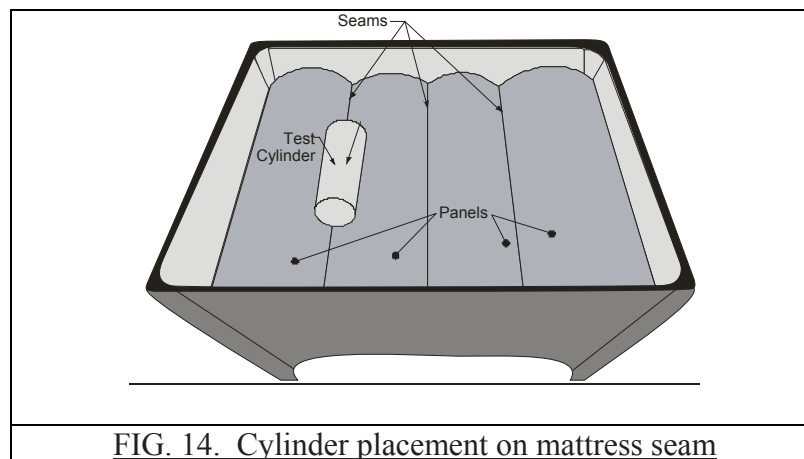
(D) 7.10.1.3 Place the infant test cylinder, as shown in Fig. 13, in the center of the 1st seam (the seam between an end panel and its adjacent panel), as shown in Fig. 14, and allow the cylinder to come to rest in the seam.

Note to Paragraph (b)(9)(i)(D): If the cylinder begins to roll out of the seam, place a stop(s) on the mattress surface against the cylinder to prevent movement. The stop(s) shall not influence the angle measurement and shall have a total weight no greater than 0.25 lbs.

(E) Figure 13. Infant Test Cylinder.



(F) Figure 14. Cylinder placement on mattress seam.



(G) 7.10.1.4 Place a 6"x 4" x 1/2" (152 x 101.6 x 12.7 mm) nominal thickness steel block weighing 3.3 lbs. (+/- 0.2 pounds) on the mattress panel in front of the cylinder with the 6" length of the block in line with the center line of the cylinder as shown in Fig. 15. Place the block within 1/2" (12.7 mm) of the cylinder. If the block slides and touches the cylinder, this is allowable.

(H) 7.10.1.4.1 Where the play yard bassinet size constraints do not allow for placement of the steel block in front of the cylinder, move the cylinder off center, enough to allow placement of the block, as outlined above in 7.10.1.4.

(I) 7.10.1.5 Place the inclinometer in the center of the block, and measure the angle formed with the horizontal along the line that is perpendicular to the longitudinal axis of the cylinder, as shown in Fig. 16. Ensure the inclinometer does not touch the mattress surface.

Note to Paragraph (b)(9)(i)(I): If needed, an additional level block of negligible mass, no greater than 0.2 lb, may be placed atop the steel block in order to elevate the inclinometer, such that it does not touch the mattress surface.

(J) Figure 15. Steel block in front of the cylinder for a single occupant bassinet

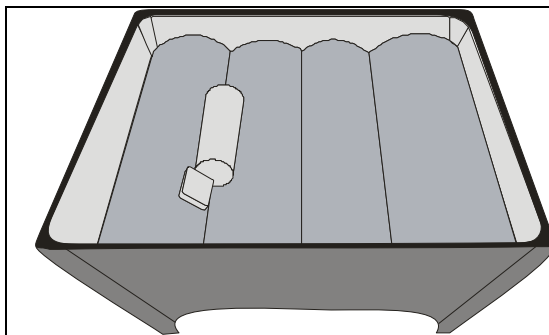


FIG. 15. Steel block in front of the cylinder for a single occupant bassinet

(K) Figure 16. Inclinometer on steel block in front of the cylinder for a single occupant bassinet.

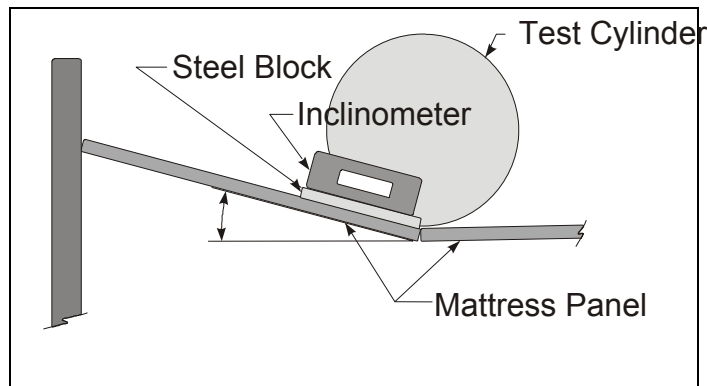


FIG.16. Inclinometer on steel block in front of the cylinder for a single occupant bassinet

(L) 7.10.1.6 Record the angle measurement.

(M) 7.10.1.7 Repeat 7.10.1.4–7.10.1.5 on the opposite side of the seam and record the measurement.

(N) 7.10.1.8 Remove the cylinder from the bassinet.

(O) 7.10.1.9 Repeat 7.10.1.3–7.10.1.8 on each remaining seam of the mattress and record the angles.

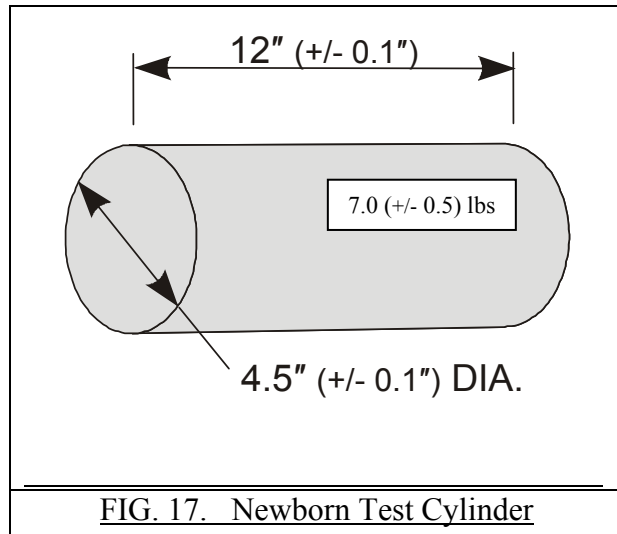
(P) 7.10.2 Angle measurement for bassinets intended for two occupants:

(Q) 7.10.2.1 Establish a horizontal reference plane by placing an inclinometer, with an accuracy capable of 0.5° minimum resolution, on the floor of the testing area and zeroing it.

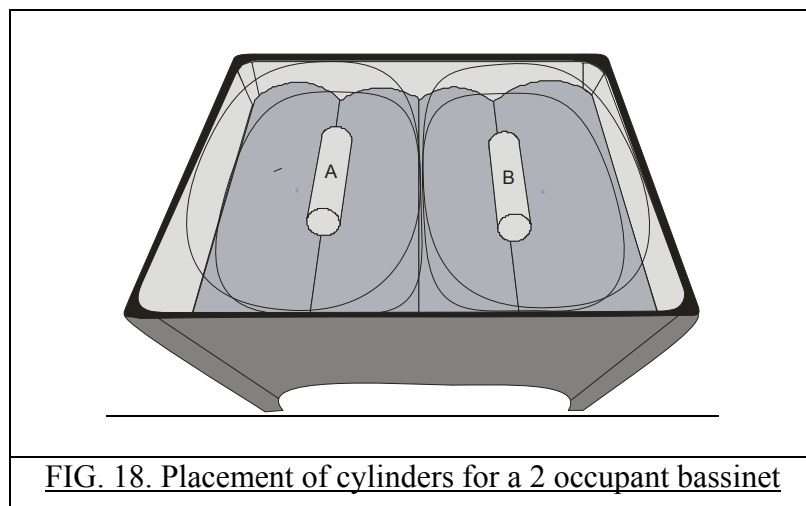
(R) 7.10.2.2 Place one at a time, two identical newborn test cylinders (A and B), as shown in Fig. 17 in the occupant retention areas, as shown in Fig. 18, and allow them to come to rest in the seam.

Note to Paragraph (b)(9)(i)(R): If the cylinder begins to roll out of the seam place a stop(s) on the mattress surface against the cylinder to prevent movement. The stop(s) shall not influence the angle measurement and shall have a total weight no greater than 0.25 lbs.

(S) Figure 17. Newborn Test Cylinder



(T) Figure 18. Placement of cylinders for a 2 occupant bassinet



(U) 7.10.2.3 Apply a 10.0 ± 0.5 lb compression force simultaneously with a force gauge onto the center of each cylinder, and hold for 10 seconds.

(V) 7.10.2.4 Place a 6"x 4" x 1/2" (152 x 101.6 x 12.7 mm) nominal thickness steel block weighing 3.3 lbs. (+/- 0.2 pounds) on the mattress panel in front of cylinder A with the 6" length of the block in line with the center line of the cylinder, as shown in Fig. 19. Place the

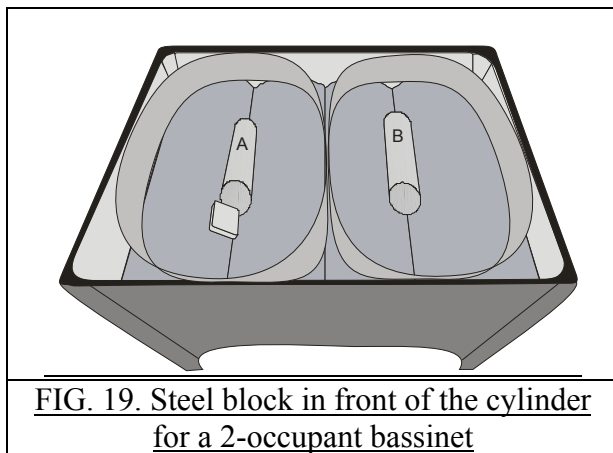
block within $\frac{1}{2}$ " (12.7 mm) of the cylinder. If the block slides and touches the cylinder, this is allowable.

(W) 7.10.2.4.1 Where the play yard bassinet size constraints do not allow for placement of the steel block in front of the cylinder, move the cylinder off center enough to allow placement of the block as outlined above in 7.10.2.4.

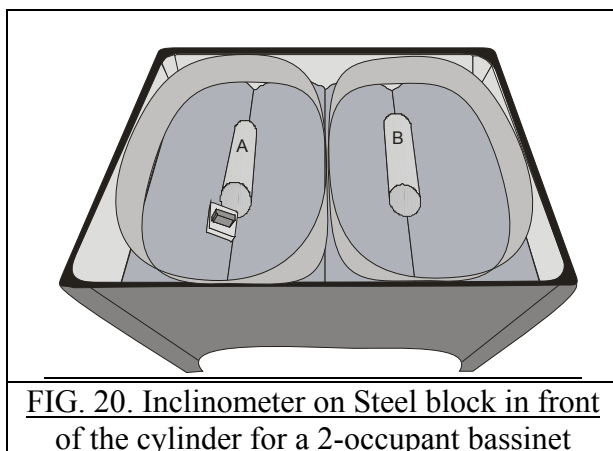
(X) 7.10.2.5 Place the inclinometer on the block, and measure the angle formed with the horizontal along the line that is perpendicular to the longitudinal axis of cylinder A, as shown in Fig. 20. Ensure that the inclinometer does not touch the mattress surface.

Note to Paragraph (b)(9)(i)(X): If needed, an additional level block of negligible mass, no greater than 0.2 lb, may be placed atop the steel block in order to elevate the inclinometer, such that it does not touch the mattress surface.

(Y) Figure 19. Steel block in front of the cylinder for a 2-occupant bassinet.



(Z) Figure 20. Inclinometer on Steel block in front of the cylinder for a 2-occupant bassinet.



(AA) 7.10.2.6 Record the angle measurement.

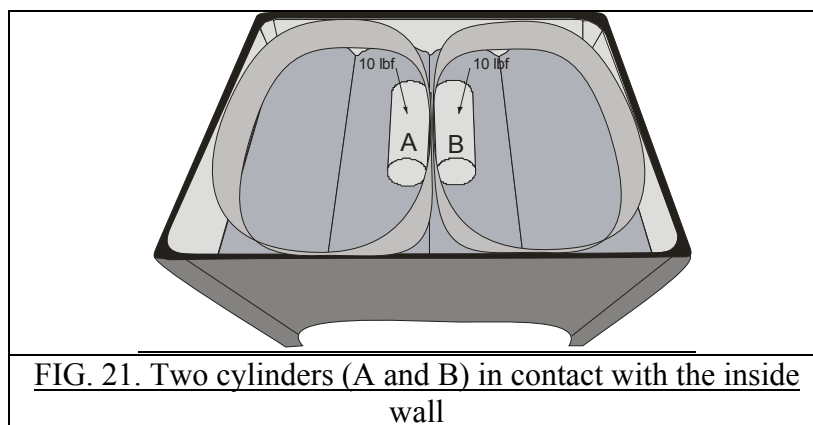
(BB) 7.10.2.7 Repeat 7.10.2.4–7.10.2.5 on the opposite side of the cylinder and record the measurement.

(CC) 7.10.2.8 Repeat the angle measurements 7.10.2.4–7.10.2.7 for cylinder B and record the measurement.

(DD) 7.10.2.9 Remove both cylinders and then place them in the occupant retention areas such that the side of the cylinders are in contact with the inside wall as shown in Fig. 21.

(EE) 7.10.2.10 Apply a 10.0 ± 0.5 lb compression force simultaneously with a force gauge onto the center of each cylinder and hold for 10 seconds.

(FF) Figure 21. Two cylinders (A and B) in contact with the inside wall.



(GG) 7.10.2.11 Place 6"x 4" x 1/2" (152 x 101.6 x 12.7 mm) nominal thickness steel block weighing 3.3 lbs. (+/- 0.2 pounds) on the mattress panel on one side perpendicular to the longitudinal axis of the cylinder, with the centerline of the block adjacent to the midpoint of the cylinder. Place the block within 1/2" (12.7 mm) of the cylinder. If the block slides and touches either the inside wall or the cylinder, this is allowable.

(HH) 7.10.2.12 Place the inclinometer in the center of the block, and measure the angle formed with the horizontal along the line that is perpendicular to the longitudinal axis of cylinder A as shown in Fig. 22.

(II) 7.10.2.13 Record the angle measurement.

(JJ) 7.10.12.14 Place a 6"x 4" x 1/2" (152 x 101.6 x 12.7 mm) nominal thickness steel block weighing 3.3 lbs. (+/- 0.2 pounds) on the mattress panel on one side perpendicular to the longitudinal axis of the cylinder, with the centerline of the block adjacent to the midpoint of the cylinder. Place the block within 1/2" (12.7 mm) of the cylinder. If the block slides and touches the cylinder, this is allowable.

(KK) 7.10.12.15 Place the inclinometer in the center of the block, and measure the angle formed with the horizontal along the line that is perpendicular to the longitudinal axis of cylinder B, as shown in Fig. 23.

(LL) 7.10.2.16 Record the angle measurement.

(MM) Figure 22. Angle measure in front of Cylinder A.

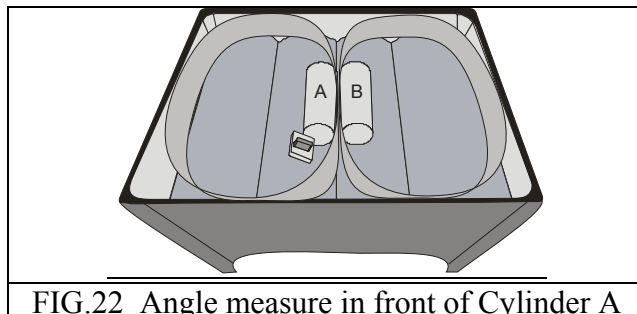
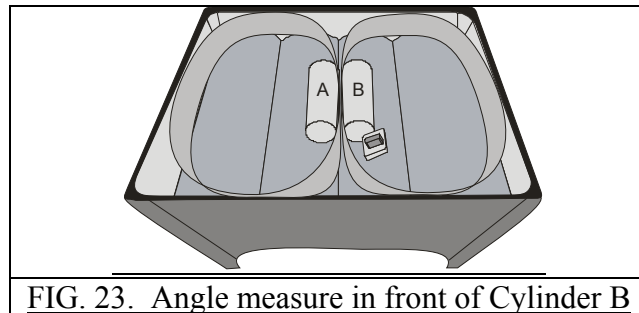


FIG.22 Angle measure in front of Cylinder A

(NN) Figure 23. Angle measure in front of Cylinder B.



(OO) *Rationale.* (1) The cylinder used in 7.10.1 was copied from a European standard for baby walkers (EN 1273:2005) and appears to be based on the weight and torso dimensions of a child between 6 and 8 months old. This represents the heaviest intended occupant, which will result in a more conservative test.

(2) Because bassinet accessories intended for multiple births will have a shorter useful range of utility, the larger cylinder used in 7.10.2 was too heavy to represent the intended user population. The smaller cylinder used in 7.10.2 was based on the weight of an infant, matched to the height of the test cylinder in 7.10.1.

(ii) [Reserved]

(10) In addition to the changes to ASTM F 2194-12 in paragraph (b)(10) of this section comply with the following:

(i) 7.11 *Removable Bassinet Bed Attachment Tests.*

(A) 7.11.1 Assemble the bassinet/cradle base/stand only, in accordance with manufacturer's instructions.

(B) 7.11.2 Place the base/stand in one of the manufacturer's recommended use positions.

(C) 7.11.3 Place the base/stand and the inclinometer on a flat level horizontal surface ($0 \pm 0.5^\circ$) to establish a test plane. Zero the inclinometer.

(D) 7.11.4 Remove the mattress pad from the bassinet bed.

NOTE to Paragraph (b)(10)(i)(D) —For mattresses that are integral with the mattress support, do not remove the mattress and perform all angle measurements for 7.11 on a 6 by 6 by 3/8-in. nominal aluminum block placed on the center of the mattress.

(E) 7.11.5 Place the bassinet bed on the base/stand in the intended use orientation without engaging any latch or lock mechanism. If the bassinet bed can rest on the base/stand in its intended use orientation in more than one lateral unlocked position (see Figure 24), the unit shall be evaluated in the lateral position most likely to fail the requirements outlined in 6.10.

(F) Figure 24: Bassinet Bed Resting on Stand, Showing Possible Alternate Lateral Positions.

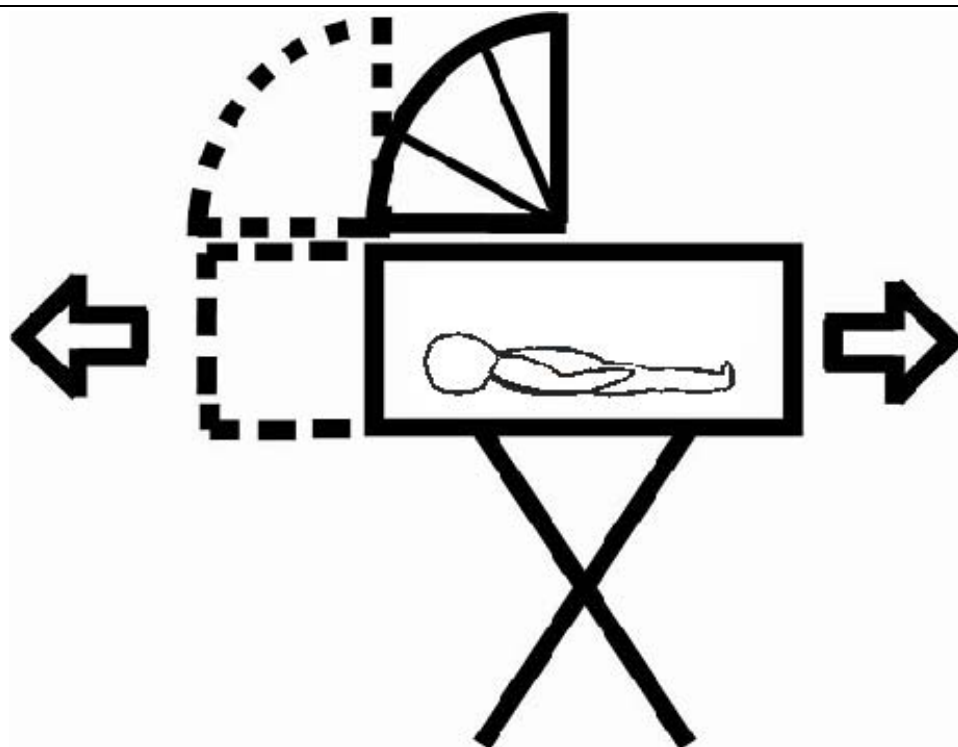


Figure 24: Bassinet Bed Resting on Stand,
Showing Possible Alternate Lateral Positions

(G) 7.11.5.1 If the base/stand supports the bassinet bed, place the inclinometer on the mattress support at the approximate center of the mattress support. Care should be taken to avoid seams, snap fasteners, or other items that may affect the measurement reading. Record the angle measurement.

(H) 7.11.5.2 If the base/stand supports the bassinet bed and the angle of the mattress support surface is less than 20 degrees of horizontal, evaluate whether the bassinet has a visual indicator per 6.10.4.

(I) 7.11.5.3 If the base/stand supports the bassinet bed, and the angle of the mattress support surface is less than 20 degrees of horizontal, and the bassinet does not contain a false latch/lock indicator, test the unit in accordance with sections 7.4.2-7.4.7.

(J) 7.11.6 Repeat 7.11.3 through 7.11.5.3 for all of the manufacturer's base/stand positions.

(K) 7.11.7 If the product design allows, repeat 7.11.2 through 7.11.6 with the bassinet bed rotated 180° from the normal use orientation.

(I) *Rationale.* This test requirement addresses fatal and nonfatal incidents involving bassinet beds that tipped over or fell off their base/stand when they were not properly locked/latched to their base/stand or the latch failed to engage as intended. Products that appear to be in an intended use position when the lock or latch is not properly engaged can create a false sense of security by appearing to be stable. Unsecured or mis-aligned lock/latch systems are a hidden hazard because they not easily seen by consumers due to being located beneath the bassinet or covered by decorative skirts. In addition, consumers will avoid activating lock/latch

mechanisms for numerous reasons if a bassinet bed appears stable when placed on a stand/base. Because of these foreseeable use conditions, this requirement has been added to ensure that bassinets with a removable bassinet bed feature will be inherently stable or it is obvious that they are not properly secured.

(2) Section 6.10 allows bassinet bed designs that:

(i) Cannot be supported by the base/stand in an unlocked configuration,

(ii) Automatically lock and cannot be placed in an unlocked position on the base/stand,

(iii) Are clearly and obviously unstable when the lock/latch is misaligned or unused,

(iv) Provide a visual warning to consumers when the product is not properly locked onto the stand/base, or

(v) Have lock/latch mechanisms that are not necessary to provide needed stability.

(ii) [Reserved]

Dated: October 4, 2012.

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission

